

GEOFFREY S. BERMAN
United States Attorney
Southern District of New York
By: JEFFREY K. POWELL
MÓNICA P. FOLCH
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
(212) 637-2800
jeffrey.powell@usdoj.gov
monica.folch@usdoj.gov

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, the States of
CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII,
ILLINOIS, INDIANA, IOWA, LOUISIANA,
MARYLAND, MASSACHUSETTS, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
JERSEY, NEW MEXICO, NEW YORK, NORTH
CAROLINA, OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VERMONT, VIRGINIA,
WASHINGTON, WISCONSIN, and the DISTRICT
OF COLUMBIA *ex rel.* URI BASSAN,

Plaintiffs,

v.

OMNICARE, INC.,

Defendant.

UNITED STATES OF AMERICA,

Plaintiff,

v.

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

15 Civ. 4179 (CM)

COMPLAINT-IN-INTERVENTION
OF THE UNITED STATES OF
AMERICA

JURY TRIAL DEMANDED

The United States of America (the “Government”), by and through its attorney Geoffrey S. Berman, United States Attorney for the Southern District of New York, brings this Complaint-In-Intervention seeking damages and penalties against Omnicare, Inc. (“Omnicare”) and its parent company, CVS Health Corporation (“CVS”), under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the “FCA”), and, in the alternative, under the common law, and alleges as follows:

PRELIMINARY STATEMENT

1. From 2010 to 2018 (the “Relevant Period”), Omnicare—the country’s largest provider of pharmacy services to long-term care facilities—fraudulently billed Medicare, Medicaid, and TRICARE for hundreds of thousands of non-controlled drugs dispensed without valid prescriptions to elderly and disabled residents of thousands of assisted living facilities, group homes for individuals with special needs, independent living communities, and other residential long-term care facilities.

2. Omnicare, and its parent company CVS, allowed Omnicare pharmacies to dispense prescription drugs indefinitely to individuals living in these residential facilities based on prescriptions that had expired, were out of authorized refills, or were otherwise invalid. Omnicare disregarded prescription refill limitations and expiration dates—which would have triggered consultation with residents’ treating physicians to evaluate whether the dispensed drugs should be renewed—and instead continued to push drugs out the door based on stale, invalid prescriptions.

3. Rather than performing its basic professional obligation as a pharmacy to obtain a new prescription after an old one expired or ran out of refills, Omnicare simply assigned a new

number to the old prescription and kept on dispensing, as if a new prescription had been obtained. Omnicare referred to this as a “rollover” prescription. In at least 1,766 residential facilities, Omnicare allowed prescriptions to “roll over.” And in at least an additional 1,476 residential facilities, Omnicare “rolled over” prescriptions through its “cycle fill” system, an automated system used to refill large volumes of medications in bulk on a periodic basis. Often, even Omnicare’s first dispensation of a drug was based on records that were not valid, legal prescriptions from healthcare providers with prescriptive authority.

4. Omnicare operates approximately 160 pharmacies across the country that collectively dispense tens of millions of prescription drugs to well over one million patients a year. Omnicare “rolled over” prescriptions so that it could push its product out the door as fast as possible. Omnicare management consistently prioritized speed and revenues over sound clinical practice, often ignoring Omnicare’s fundamental obligation as a pharmacy to ensure that drugs are given to patients only pursuant to valid prescriptions.

5. Omnicare and CVS failed to ensure that Omnicare’s large network of pharmacies reliably tracked when prescriptions expired and obtained new prescriptions when necessary. Omnicare did not adequately train pharmacy staff on what constitutes a valid prescription or how to use Omnicare’s computer dispensing systems to prevent dispensations based on expired prescriptions. All the while, Omnicare managers exerted excessive pressure on overwhelmed pharmacy staff to dispense quickly so that Omnicare could submit claims and collect payments.

6. This is not the first time Omnicare’s dispensing practices have come under fire. Omnicare has been subject to numerous federal investigations and lawsuits over the years, many of which have resulted in substantial settlements. For instance, Omnicare entered into a \$50

million settlement in 2012 after a Department of Justice investigation found that its pharmacies had dispensed controlled substances to long-term care facility residents without valid prescriptions. Yet, even after this investigation and settlement, Omnicare continued to dispense non-controlled prescription drugs illegally.

7. Senior management at Omnicare and CVS knew Omnicare's pharmacies were routinely dispensing drugs without valid prescriptions. But they failed to begin to address the problem until they found out Omnicare was being investigated again, this time by this Office.

8. Several state boards of pharmacy alerted Omnicare that its pharmacies were illegally dispensing drugs without valid prescriptions. For example, in 2015, the New Mexico Board of Pharmacy investigated Omnicare's Albuquerque pharmacy and found that "medications were being dispensed after refills had run out" and that "prescription medications were being dispensed pursuant to drug orders which did not have quantities, refills, and in some cases a prescriber's signature." These practices were "serious violations of the New Mexico Board of Pharmacy's statutes and regulations requiring retail pharmacies to dispense medications only pursuant to prescriptions which contain all of the elements of a prescription." CVS's Director of Regulatory Affairs was made aware of these findings.

9. Internal audits found that Omnicare pharmacies often lacked valid prescriptions to support drug dispensations. For example, a 2012 draft report summarizing an Omnicare audit of pharmacy processes and controls reported a "recurring issue" identified in multiple operational audits that year: "Renewal physician orders are not consistently obtained due to the lack of an automated process to prevent the pharmacy from dispensing an order beyond 12 months." This draft report was circulated to several compliance officers, including Omnicare's Chief

Compliance Officer, who did nothing to correct the problem.

10. Omnicare's own pharmacists complained to management about "rollover" dispensations. For instance, one pharmacist who worked in an Ohio Omnicare pharmacy from 2011 until 2018 reported that she and others repeatedly complained to management that Omnicare was not tracking whether a prescription had any authorized refills before dispensing drugs to residential facilities. But Omnicare management ignored those complaints.

11. Omnicare's Compliance Department succinctly acknowledged the dispensing problem in an April 2015 email exchange among senior compliance officers, in which one Regional Compliance Officer stated: "An issue that I am running into more and more in multiple states concerns the ability of our systems to allow prescriptions to continue to roll after a year to a new prescription number without any documentation or pharmacist intervention." A compliance officer then forwarded the email to the head of Omnicare's Third Party Audit group, who responded that she had a "potential solution (programmed last year) *but no one is rolling it out now.*" (Emphasis added.)

12. Omnicare's practice of illegally dispensing drugs to elderly and disabled individuals living in residential facilities exposed these vulnerable individuals to a significant risk of harm. Many of the prescription drugs dispensed by Omnicare without valid prescriptions treat serious, chronic conditions, such as dementia, heart disease, and diabetes. They include antipsychotic drugs, anticonvulsant medications, cardiovascular drugs, and other medications that can have dangerous side effects and need to be closely monitored by doctors. This is particularly true for elderly and disabled patients, who are commonly on multiple drugs at the same time and thus face increased risks of side effects and adverse drug interactions.

13. In contrast to traditional skilled nursing homes, where residents have access to 24-hour medical care supervised by physicians, assisted living and other residential facilities offer more limited medical care or none at all. In particular, these facilities generally do not have physicians on staff to oversee and monitor residents' drug therapy. Rather, residents in these communities typically rely on their own doctors, outside of the facilities, to prescribe drugs, monitor the drugs' effects, and determine whether they should stop taking a drug or alter the dosage or frequency with which a drug is taken. By repeatedly dispensing potent drugs without current and valid prescriptions to elderly and disabled individuals living in residential facilities, Omnicare jeopardized the health and safety of tens of thousands of people who continued to take the same drugs for months, and sometimes years, without consulting their physician to determine whether that medication was still clinically appropriate.

14. A large percentage of the long-term care residents serviced by Omnicare are beneficiaries of federal healthcare programs, including Medicare, Medicaid, and TRICARE (collectively, "Federal Healthcare Programs"). By routinely dispensing drugs to individuals in residential facilities without valid prescriptions, Omnicare presented, or caused to be presented, hundreds of thousands of false claims to Federal Healthcare Programs, as well as contracted Medicare Part D plans, Medicaid Managed Care Organizations, and pharmacy benefit managers ("PBMs") (collectively, "Government Payors"). These claims were ineligible for reimbursement. In addition, Omnicare knowingly transmitted false information to Government Payors that made it appear that drug dispensations were supported by current, valid prescriptions from physicians when in fact they were not because any underlying prescription had expired, was out of refills, or was otherwise invalid.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the claims brought under the FCA pursuant to 31 U.S.C. § 3730(a), and 28 U.S.C. §§ 1331 and 1345, and over the common law claims pursuant to 28 U.S.C. § 1345.

16. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

17. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because Defendants transact business in this District, and a substantial part of the events giving rise to this Complaint occurred within this District. Omnicare submitted claims for prescription drugs dispensed to individuals who lived in residential facilities in this District.

PARTIES

18. Plaintiff is the United States of America. Through its agencies, the Government administers the Federal Healthcare Programs. More specifically, the United States Department of Health and Human Services (“HHS”) and its component agency, the Centers for Medicare and Medicaid Services (“CMS”), administer the Medicare and Medicaid programs, and the Department of Defense administers the TRICARE program (“TRICARE”).

19. Relator Uri Bassan is a pharmacist who previously worked as the Pharmacist-in-Charge at an Omnicare pharmacy in Albuquerque, New Mexico. In June 2015, Mr. Bassan filed an action pursuant to the FCA and comparable state and local false claims acts alleging that Omnicare dispensed prescription drugs for assisted living residents without valid prescriptions and consequently caused false claims to be submitted to Federal Healthcare Programs in violation of the FCA. Mr. Bassan is a resident of New Mexico.

20. Defendant Omnicare, Inc. is the nation's largest provider of pharmacy services to long-term care facilities. Omnicare has approximately 13,000 employees and operates approximately 160 pharmacies in 47 states across the United States. Every year, Omnicare dispenses tens of millions of prescription drugs to residents of long-term care facilities across the country, including non-skilled residential facilities located in this District. A large percentage of Omnicare's drug dispensations are to Federal Healthcare Program beneficiaries. During the Relevant Period, Omnicare submitted well over 35 million claims seeking payment for non-controlled drugs dispensed to Medicare beneficiaries residing in assisted living facilities alone. Omnicare is incorporated in Delaware and has a principal place of business in Ohio. Omnicare is a wholly-owned subsidiary of CVS.

21. Defendant CVS Health Corporation owns thousands of retail pharmacies throughout the country, and operates more than 1,000 walk-in medical clinics. CVS also serves an estimated 38 million people through health insurance products and related services, including Medicare Advantage offerings and a standalone Medicare Part D prescription drug plan. CVS acquired Omnicare in May 2015 for approximately \$12.7 billion. Shortly after the acquisition, CVS assumed an active role in overseeing Omnicare's operations, including pharmacy dispensing practices and systems.

THE FALSE CLAIMS ACT

22. The FCA establishes treble damages liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or "knowingly conceals or knowingly and

improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1).

23. “Knowingly” is defined to include actual knowledge, reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

24. Section 6402(a) of the Patient Protection and Affordable Care Act of 2010 (Enhanced Medicare and Medicaid Program Integrity Provisions), Pub. L. No. 111-148, 124 Stat. 119, 753-56 (2010), amended the Social Security Act by adding a new provision that addresses what constitutes an overpayment under the FCA in the context of a federal healthcare program. Under this section, an overpayment is defined as “any funds that a person receives or retains under [Title XVIII or XIX] to which the person, after applicable reconciliation, is not entitled under such subchapter.” 42 U.S.C. § 1320a–7k(d)(4)(B). In addition, this provision specifies in relevant part that an “overpayment must be reported and returned” within “60 days after the date on which the overpayment was identified.” 42 U.S.C. § 1320a–7k(d)(2). Failure to return any overpayment constitutes a reverse false claim actionable under section 3729(a)(1)(G) of the FCA.

25. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or false claim. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), the FCA civil penalties are \$5,500 to \$11,000 for violations occurring on or after September 29, 1999, but before November 2, 2015, *see* 64 Fed. Reg. 47099, 47103 (1999), and \$11,181 to \$22,363 for violations occurring on or after November 2, 2015, *see* 83

Fed. Reg. 3944, 3945 (2018); 28 CFR § 85.5.

THE FEDERAL HEALTHCARE PROGRAMS

A. Medicare Part D

26. Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 *et seq.* (“Medicare Program”). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D.

27. Under Medicare Part D, HHS, through its component agency, CMS, contracts with private companies (or “Part D sponsors”) to administer prescription drug plans. The Part D sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, subcontract with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

28. Generally, when an authorized healthcare provider writes a prescription for a patient who is a Medicare beneficiary, that prescription is submitted to a pharmacy to be filled. When the pharmacy dispenses the prescription drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary’s Part D sponsor (usually through the sponsor’s PBM). The claim submission includes basic information about the dispensation, including the Medicare beneficiary’s name, the prescriber, the date the prescription was written, how the prescription was transmitted to the pharmacy (*i.e.*, whether the prescription was transmitted as an electronic prescription, by phone, by fax, or as a written paper copy), quantity dispensed, the

number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under Medicare Part D.

Thereafter, the pharmacy receives reimbursement from the Part D sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary.

29. Part D sponsors are only permitted to provide benefits for Part D drugs “that require a prescription if those drugs are dispensed upon a valid prescription.” 42 C.F.R. § 423.104(h). A prescription is only valid if it “complies with all applicable State law requirements constituting a valid prescription.” 42 C.F.R. § 423.100. Pharmacies and Part D sponsors must maintain records of such prescriptions for a period of at least 10 years. 42 CFR §§ 423.505(d), 423.504(i).

30. The Part D sponsor is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event (“PDE”), which contains data regarding the prescription claim, the prescriber of the drug, how the prescription was transmitted to the pharmacy, the number of times the prescription was filled, the quantity dispensed, the amount paid to the pharmacy, and information on drug coverage under Medicare Part D.

31. Payments to a Part D sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS’s instructions for the submission of Part D prescription PDE claims data state that “information . . . necessary to carry out this subpart” includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims

received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

32. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. *See* 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS determines that it underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS, or by CMS to the plan, related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

33. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

34. In order to receive Part D funds from CMS, Part D sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply

with all applicable federal laws, regulations, and CMS instructions.

35. By statute, all contracts between a Part D sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

36. Medicare Part D sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA. 42 C.F.R. § 423.505(h)(1).

37. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Part D sponsors include a provision in which the sponsor “agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of [the FCA].”

38. CMS regulations further require that all subcontracts between Part D sponsors and downstream entities (such as pharmacies like Omnicare and CVS and PBMs) contain language obligating the entity to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

39. A Part D sponsor also is required by federal regulation to certify to the accuracy, completeness, and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled “Certification of data that determine payment,” provides in relevant part:

(1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who

reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. . . .

42 C.F.R. § 423.505(k).

40. Compliance with the regulatory requirement that the PDE data submitted to CMS is true, accurate, and complete is a condition of payment under the Medicare Part D program.

41. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor (“Attestation”). This Attestation states:

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:

The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the

Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

42. All approved Part D sponsors who receive payment under Medicare Part D submit these required Attestations in the same or similar format.

43. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

B. Medicaid

44. Medicaid is a joint federal-state program created in 1965 that provides healthcare

benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

45. As with Medicare, Medicaid coverage only extends to “prescribed drugs,” and does not include drugs dispensed pursuant to invalid prescriptions. *See* 42 U.S.C. § 1396d(a)(12).

46. The federal portion of each state’s Medicaid payments, known as the Federal Medical Assistance Percentage (“FMAP”), is based on the state’s per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the “total amount expended . . . as medical assistance under the State plan.” 42 U.S.C. § 1396b(a)(1).

47. Once a Medicaid beneficiary submits a prescription to a pharmacy, the pharmacy submits a claim to Medicaid and then dispenses the drug. The claim submission typically includes basic information about the dispensation, including the information about the prescriber, the date the prescription was written, how the prescription was transmitted to the pharmacy, the quantity prescribed, the number of refills authorized, the designation of the number of times the prescription has been filled (0 for original fill the corresponding number if it is a refill), the amount claimed for reimbursement, and information on drug coverage under Medicaid.

48. The vast majority of states award contracts to private companies to evaluate and

process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

49. Providers who participate in the Medicaid program, including pharmacies like Omnicare and CVS, must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that it will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

50. Furthermore, in many states, Medicaid providers, including pharmacies, must affirmatively certify, as a condition of payment of the claims submitted to Medicaid for reimbursement, compliance with applicable federal and state laws and regulations.

51. In New York, for example, pharmacies must periodically sign a “Certification Statement for Provider Billing Medicaid,” in which the pharmacy certifies that claims submitted “to the State’s Medicaid fiscal agent, for services or supplies furnished,” “will be subject to the

following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations.”

52. Although many providers are direct enrollees in the Medicaid program, several states have transitioned into Managed Care. Under Managed Care, states make Medicaid services available to recipients through health plans provided by Medicaid Managed Care Organizations (“MCOs”) that contract with the states.

53. Medicaid pays MCOs a monthly “capitation payment” to provide a bundle of services to Medicaid recipients enrolled in the Medicaid MCO plan. Services provided by MCOs, including prescription drug coverage, depend on their members’ medical needs. Some states allow for individual formularies, while other have a unified Preferred Drug List for all of their members regardless of MCO enrollment or fee-for-service coverage.

54. Under Managed Care, third party administrators under contract with MCOs, such as PBMs, send Medicaid reimbursement payments to pharmacies enrolled with, or pre-approved by, the MCOs.

55. A Medicaid beneficiary obtains his or her prescription medications from a pharmacy authorized by the beneficiary’s MCO. The pharmacy presents the prescription drug claim under the beneficiary’s Medicaid identification number to the PBM.

56. The PBM receives funds to pay Medicaid claims from the MCOs’ monthly capitation payments; this money is ultimately used to pay the claims presented by the pharmacy for Medicaid reimbursement.

57. The claims for payment submitted to MCOs are deemed to be “claims’ under the

FCA since the managed care plan is a “contractor, grantee, or other recipient,” the money is being used “to advance a Government program or interest,” and the Government provides or has provided a portion of the money requested or will reimburse the MCO for a portion of the money requested

58. Pharmacies authorized to provide services to recipients of an MCO also agree to comply with any requirements for participation as a provider in the state.

59. For example, in New York, a standard PBM contract requires pharmacies to agree to “comply with all applicable Laws, including but not limited to those Laws referenced in the Federal and State Laws and Regulations section . . . set forth in the [PBM] Provider Manual,” in which a provider agrees “to comply fully and abide by the rules, policies and procedures that the MCO . . . has established or will establish to meet general or specific obligations placed on the MCO by statute, regulation, or [state agency] guidelines or policies.”

C. TRICARE

60. TRICARE (formerly known as CHAMPUS) is part of the United States military’s healthcare system, designed to maintain the health of active duty service personnel, provide healthcare during military operations, and offer healthcare to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense, is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE contracts with PBMs to administer its retail and mail order pharmacy programs.

61. When a TRICARE beneficiary's prescription is submitted to a TRICARE network pharmacy like Omnicare, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription medication is delivered to the patient (and not returned to the shelf by the pharmacy), the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the prescriber's identity, the date the prescription was written, the number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under TRICARE.

62. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

63. TRICARE network pharmacy providers are required to maintain all TRICARE prescription records and supporting documentation for a minimum of 10 years.

64. Since 2004, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc., to administer TRICARE's network pharmacy program.

65. All pharmacies that provide services to TRICARE beneficiaries are required to

comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Billing for costs for non-covered services is included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(2). More specifically, under TRICARE regulations, "[m]isrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered the services" are "presumed to be fraud." *Id.* § 199.2(c)(6).

FACTUAL BACKGROUND

I. Prescription Drugs Can Only Be Dispensed Pursuant To Valid Prescriptions Under The Supervision Of A Physician.

66. A prescription drug is a drug which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1).

67. In light of the health risks associated with prescription drugs, they must "be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist." 21 U.S.C. § 353(b)(1).

68. Prescription drugs are divided into two broad categories: controlled substances and non-controlled prescription drugs. This action is focused on Omnicare's dispensation of non-

controlled prescription drugs.

69. A licensed healthcare provider can only authorize the dispensation of prescription drugs after determining that the prescription medication is appropriate to treat the patient.

70. Pharmacies like Omnicare have an independent obligation to dispense prescription drugs directly to patients in a safe and reliable manner, as authorized by a valid prescription. *See, e.g.*, 21 U.S.C. § 353(b)(1); N.Y. Educ. Law § 6801 (“The practice of the profession of pharmacy is defined as the . . . dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority.”).

II. Omnicare Dispensed Prescription Drugs To Residents Of Different Types Of Long-Term Care Facilities Offering Differing Levels Of Medical Care.

71. Omnicare’s pharmacies dispense and deliver prescription drugs exclusively to residents of different types of long-term care facilities.

A. Skilled Nursing Facilities Provide Around-The-Clock Medical Care Supervised By Physicians.

72. Most of Omnicare’s dispensations go to residents of skilled nursing facilities (“SNFs”). SNFs are healthcare institutions that typically provide nursing care 24 hours a day and regular physician care.

73. SNFs are primarily regulated under federal law. As healthcare institutions providing skilled medical care, certified SNFs must, for instance, designate a licensed physician to serve as medical director of the facility to implement resident care policies and coordinate medical care. SNFs must also ensure that the medical care of each patient is supervised by a licensed physician, and they must provide nursing care on a 24-hour basis. SNFs are also required to provide or obtain laboratory services as well as radiology and other diagnostic

services for their patients. *See generally* 42 C.F.R. Part 483, Subpart B.

B. Assisted Living Facilities And Other Residential Facilities Provide Limited Or No Medical Care.

74. Omnicare also dispenses prescription drugs to residents of residential long-term care facilities. According to the National Institute on Aging, residential facilities generally “provide services to individuals who cannot live independently but generally do not require the skilled level of care provided by nursing homes.” Because different types of residential facilities serve different resident populations, they provide a variety of services.

75. For example, independent living facilities typically offer a residential setting for seniors who do not need assistance with personal or medical care. These facilities may provide planned community events, excursions, and other social or recreational activities.

76. Adult homes or group homes serve individuals who are unable to live independently, sometimes because they have developmental disabilities or other special needs. These supportive settings typically provide 24-hour supervision, daily meals, personal care, and housekeeping. They also sometimes provide social services by trained staff.

77. By far the most common type of residential community served by Omnicare is the assisted living facility, or “ALF.” Assisted living facilities generally serve elderly residents who require assistance with daily activities such as bathing, dressing, and using the bathroom.

According to the National Institute on Aging:

Assisted living is for people who need help with daily care, but not as much help as a nursing home provides. . . . Assisted living residents usually live in their own apartments or rooms and share common areas. They have access to many services, including up to three meals a day; assistance with personal care; help with medications, housekeeping, and laundry; 24-hour supervision, security, and on-site staff; and social and recreational activities.

78. Some residential facilities are located within larger communities that offer other types of long-term care. For example, continuing care retirement communities sometimes provide three distinct facilities in one: a skilled nursing facility, an assisted living facility, and an independent living facility. A single facility may have different units or wings that offer different levels of medical care. Such communities enable residents to move to different levels of assistance and medical care as their needs change over time.

79. Despite their differences, facilities are generally considered to be “residential” facilities if their principal purpose is to provide housing in conjunction with personal care and social services, rather than continuous skilled medical care for their residents. This Complaint uses the term “Residential Facilities” to collectively refer to ALFs and other residential care facilities that do not provide the 24-hour skilled medical care available at skilled nursing facilities.

1. Assisted Living Facilities Do Not Provide Routine Physician Review Of Residents’ Prescription Drug Regimen.

80. As residential facilities that generally do not provide skilled medical care, assisted living facilities are typically not subject to the federal regulations applicable to skilled nursing facilities. Rather, ALFs are regulated under state law as residential facilities that provide personal care services to residents.

81. While specific laws regulating assisted living facilities vary somewhat from state to state, they consistently provide that ALFs are primarily residential facilities that offer limited medical services. For example:

- Under New York law, an “assisted living residence” is a facility that “provides or arranges for housing, on-site monitoring, and personal care

services and/or home care services (either directly or indirectly), in a home-like setting to five or more adult residents” as well as “daily food service, twenty-four hour on-site monitoring, case management services, and the development of an individualized service plan for each resident.” N.Y. Pub. Health Law § 4651(1).

- Under Massachusetts law, an “assisted living residence” provides “room and board” as well as assistance with activities of daily living. Mass. Gen. Laws Ann. ch. 19D, § 1. Further, “[n]o assisted living residence shall admit any resident who requires twenty-four hour skilled nursing supervision.” Mass. Gen. Laws Ann. ch. 19D, § 11.
- Under Illinois law, an “assisted living establishment” provides “community-based residential care for persons who need assistance with activities of daily living, including personal, supportive, and intermittent health-related services.” 210 Ill. Comp. Stat. Ann. 9/10. Further, individuals who have severe mental illness, who are in need of constant nursing care, or who require total assistance with two or more [activities of daily living] may not be admitted or retained in an ALF. 210 Ill. Comp. Stat. Ann. 9/75.
- Under Florida law, an “assisted living facility” means any “residential facility” that provides “housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults.” Fla. Stat. Ann. § 429.02. However, to be admitted and retained in an ALF, a resident must: not require 24-hour nursing supervision, be able to perform activities of daily living with assistance if necessary, and be able to transfer, with assistance if necessary. Fla. Admin. Code Ann. r. 59A-36.006
- Under Wisconsin law, a “community-based residential facility” is “a place where 5 or more adults . . . who do not require care above intermediate level nursing care reside and receive care, treatment or services that are above the level of room and board but that include no more than 3 hours of nursing care per week per resident.” Wis. Stat. Ann. § 50.01.

82. Consistent with these regulations, assisted living facilities do not typically provide regular care by a physician; rather, ALF staff help residents arrange appointments with the residents’ own outside healthcare providers, and facilitate the process of obtaining from pharmacies any drugs prescribed by residents’ doctors. ALF residents generally choose their own medical doctors, and those doctors are responsible for prescribing drugs for the residents and

regularly monitoring residents' drug therapy.

83. The four largest assisted living facility providers in the United States, Atria Senior Living Group, Brookdale Senior Living, Sunrise Senior Living, and Five Star Senior Living conform to this model of residential care. During the course of the Government's investigation, these ALF providers confirmed that none of the Atria, Brookdale, Sunrise, or Five Star assisted living facilities identified by the Government as having used Omnicare's pharmacy services had physicians on staff to monitor residents' medication regimens. For instance, Atria confirmed that "Atria does not contract with or retain any physician or other authorized prescriber to monitor or review medications dispensed to residents by any pharmacy, including Omnicare."

2. Assisted Living Facility Residents' Prescription Drug Therapy Must Be Closely Monitored By A Physician To Avoid Dangerous Adverse Effects.

84. Close monitoring of ALF residents' drug therapy by a licensed prescriber is critical in light of the prevalence of serious health conditions among elderly ALF residents, the dangerous side effects of the prescription drugs commonly used to treat such health conditions, and the heightened risk of adverse drug interactions among the multiple prescription drugs ALF residents typically take.

85. According to a study of long-term care facilities in the United States in 2015 and 2016 conducted by the National Center for Health Statistics, over 800,000 Americans reside in assisted living communities. The majority of these residents are 85 years old or older. Another 30% of ALF residents are 75-84 years old.

86. Although ALFs are not intended for individuals who have acute health problems, most ALF residents suffer from chronic health conditions common in elderly individuals. For

instance, according to the National Center for Health Statistics study, more than half of all ALF residents have high blood pressure; 41% are living with Alzheimer's disease or other dementias; 34.3% have heart disease; 30% have depression; and 18% have diabetes.

87. These serious, chronic conditions are commonly treated with strong prescription drugs that can have dangerous side effects. Such drugs include antipsychotic drugs, which can cause seizures, infections, and heart rhythm abnormalities; cardiovascular drugs, which can cause renal failure, dehydration, and fainting; and antidiabetic drugs, which, in elderly patients, carry a higher risk of low blood sugar events that could lead to emergency room visits.

88. Because ALF residents typically suffer from more than one chronic condition, they tend to take multiple prescription drugs at the same time. And the greater the number of drugs used by an older person, the greater the risk of adverse drug events (injuries resulting from use of a drug). Polypharmacy, which is commonly defined as the use of five or more drugs, has been associated with increased risk of hospitalization, functional impairment, and cognitive decline.

III. Prescriptions For Residents Of ALFs And Other Residential Facilities Are Only Valid For A Specified Number Of Fills And A Certain Period Of Time.

89. Pharmacies can only dispense prescription drugs if they have a valid prescription (except in emergency situations). State law determines what constitutes a valid prescription. *See* 42 C.F.R. § 423.100.

A. A Prescription Must Specify The Total Quantity Prescribed Or The Number Of Refills Authorized.

90. Although specific state requirements for valid prescriptions vary, state laws typically require that pharmacies like Omnicare obtain a prescription with at least the following information before dispensing prescription drugs: the patient's name; the date of the prescription; the name of the drug; the strength of the drug; the total quantity prescribed (which may be expressed as the number of refills allowed); and the prescriber's information and signature. *See, e.g.,* N.Y. Comp. Codes R. & Regs. tit. 8, § 29.7; Cal. Bus. & Prof. Code § 4040(a)(1)(A)-(F); Tex. Health and Safety Code § 483.001(13); Fla. Stat. § 456.42; Minn. Stat. § 151.01(16a).

91. The requirement that a prescription specify the total quantity prescribed by the doctor (*e.g.*, total number of pills, tablets, etc.) makes clear that prescriptions are not supposed to authorize an infinite amount of medication. The required limitation as to drug quantity is important to trigger opportunities for physicians to periodically assess the safety and efficacy of patients' drug therapy and stop or alter that drug therapy as necessary.

92. Thus, any document that sets forth this information and is signed by the prescriber, whether in hard copy or delivered electronically, generally constitutes a valid prescription. In long-term care pharmacies, such documents are often referred to as "retail-type" prescriptions, because they contain the same information required to fill prescriptions in retail pharmacies.

93. In general, prescriptions communicated verbally (for example, by telephone) are acceptable under state law, so long as they include the elements of a prescription (other than the prescriber signature), and are documented as verbal prescription orders by a pharmacist. *See, e.g.,* Cal. Bus. & Prof. Code § 4070; 22 Tex. Admin. Code §§ 291.34, 309.2; Fla. Stat. §

893.04(1)(a); Fla. Admin. Code. 64B16-27.103.

B. A Prescription Expires After A Specified Period, Usually One Year.

94. In addition, state laws generally provide that prescriptions for non-controlled drugs are valid for a specified period, which is typically one year after the date the prescription was written. *See, e.g.*, Fla. Admin. Code r. 64B16-27.211. (“No prescription [for a legend drug] may be filled or refilled in excess of one (1) year from the date [] the original prescription was written.”); Minn. R. 6800.3510 (“No prescription drug order may be filled or refilled more than 12 months after the date on which it was issued. Refills originally authorized in excess of 12 months are void 12 months after the original date of issuance of the prescription drug order.”); N.Y. Comp. Codes R. & Regs. tit. 18, § 505.3 (“(1) A written order may not be refilled unless the practitioner has indicated the number of allowable refillings on the order. (2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period”); Mich. Admin. Code R 338.479b (“A prescription is valid for 1 year from the date the prescription was issued.”); 49 Pa. Code § 27.18 (“Prescriptions for nonproprietary drugs may be refilled for 1 year from the date of the prescription if refills have been authorized by the prescriber.”); N.J. Admin. Code § 13:39-7.3 (“A prescription for medication or devices, which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the practitioner or the practitioner's authorized agent, and the prescription may not be filled or refilled after one year from the date the original prescription was issued.”); Ill. Admin. Code tit. 68, §§ 1330.500, 1330.520 (“No prescription may be filled or refilled for a period in excess of one year from the date of the original issuance of the prescription or order by the prescriber.”);

Utah Code R156-17b-612(9) (“Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.”).

95. In addition, a drug may only be refilled when the prescription specifically authorizes refills. *See, e.g.*, Utah Code R156-17b-612(8); Kan. Stat. Ann. § 65-1637 (“All prescriptions shall be filled or refilled in strict conformity with any directions of the prescriber.”); Minn. Stat. Ann. § 151.211 (“[A] prescription drug order may be refilled only with the written, electronic, or verbal consent of the prescriber.”).

96. The automatic expiration of a prescription is for the protection of the patients. As with the prescribed quantity requirement, the prescription’s expiration ensures that a physician (or other licensed prescriber) has the opportunity to regularly examine the patient to assess whether the drug is still medically appropriate for the patient and whether any changes should be made to the dosage.

97. Indeed, Omnicare’s own written policies prohibited pharmacies from dispensing prescription drugs to individuals in Residential Facilities more than one year after the prescription was written. Omnicare’s Long-Term Care Services and Procedures Manual, which Omnicare provided to ALFs, explicitly states: “Non-controlled medications may not be refilled 12 months after the original order has been filled and requires a new order from the Physician/Prescriber.” As explained below, Omnicare pharmacies routinely violated this policy.

98. Omnicare’s Audit Department also repeatedly informed pharmacies across the country that CMS rejected prescriptions written more than 12 months after dispensations.

C. Because SNF Resident Care Is Supervised By Physicians, Some States Permit Pharmacies To Dispense Prescription Drugs To SNFs Until The Physician Discontinues The Prescription.

99. Because skilled nursing facilities are healthcare institutions that provide round-the-clock medical care and monitoring, some states permit pharmacies to dispense prescription drugs to SNF residents based upon a prescriber's "chart order." Chart orders are typically reviewed and signed by the SNF's attending physician on a regular basis and therefore do not typically specify the total quantity prescribed or the number of refills authorized, but are considered valid prescriptions in the SNF setting. *See, e.g.*, 105 Mass. Code Regs. 700.001; S.C. Code Ann. § 40-43-30; Minn. R. 6800.0100; Neb. Rev. Stat. Ann. § 38-2810. In such states, the absence of a specified total prescribed quantity or number of authorized refills means that pharmacies may continue to dispense prescription drugs to SNF residents until the facility's attending physician discontinues the order.

100. However, even in the hospital-like setting of skilled nursing facilities, many states provide that chart orders expire after a certain amount of time. *See, e.g.*, Minn. R. 6800.3510 ("No prescription drug order may be filled or refilled more than 12 months after the date on which it was issued."); Neb. Rev. Stat. Ann. § 38-2870 ("All medical orders shall be written, oral, or electronic and shall be valid for the period stated in the medical order," except that "if the medical order is for a [non-controlled] drug or device, such period shall not exceed twelve months from the date of issuance at which time the medical order shall expire.").

IV. As Omnicare Became The Country's Largest Long-Term Care Pharmacy, It Failed To Put In Place The Staffing, Controls, And Training Necessary To Ensure Legal Dispensing Practices.

101. Leading up to the Relevant Period, Omnicare rapidly grew into a Fortune 500 company through the acquisition of dozens of pharmacies across the country. During a brief span, it spent hundreds of millions of dollars to purchase several companies that operated large networks of long-term care pharmacies throughout the country, including American Mediserve Corporation, American Pharmaceutical Services Inc., NCS HealthCare Inc., and NeighborCare.

102. Currently, Omnicare operates approximately 160 pharmacies nationwide. Every year, these pharmacies fill tens of millions of prescriptions for more than one million elderly and disabled long-term care facility residents across the country. In the second quarter of 2015 alone, Omnicare dispensed approximately 26 million prescriptions.

103. As Omnicare grew into a long-term care pharmacy behemoth, management failed to create the kind of organizational infrastructure necessary to dispense drugs to patients in a safe and reliable manner.

104. Specifically, Omnicare failed to put in place adequate systems, procedures, and training to ensure that its pharmacies fulfilled their core obligations to (i) only dispense drugs that are supported by legally valid prescriptions; (ii) accurately track when those prescriptions expire; and (iii) obtain new prescriptions when necessary.

105. Instead of putting in place comprehensive compliance and training programs to support pharmacy staff, Omnicare's management focused on maximizing the prescriptions filled by each pharmacy through its automated computer dispensing systems. Indeed, Omnicare's business strategy, as touted to its investors, was to rely on the use of automation to dispense and

deliver drugs. For example, in its 2014 10-K filing, Omnicare highlighted its use of “proprietary automation” to support prescription refills, stating: “The use of automation within our pharmacies leverages our size and, we believe, distinguishes us from our competitors by reducing our dispensing costs while improving our dispensing accuracy.”

106. Yet Omnicare left core aspects of pharmacy operations to the discretion of local pharmacy staff who frequently followed their own ad hoc dispensing practices.

A. Omnicare Pharmacies Were Under Constant Pressure To Dispense Huge Volumes Of Drugs.

107. Omnicare pharmacies processed a tremendous volume of prescriptions during the Relevant Period. Indeed, many pharmacies dispensed thousands of drugs *each day*. For example:

- A dispensing pharmacist who worked from 2012 to 2018 at an Omnicare pharmacy in Fort Worth, Texas reported that the pharmacy processed between 5,000 and 7,000 orders every day.
- A former Pharmacist-in-Charge of Omnicare of Cincinnati reported that the pharmacy filled 54,000 prescriptions every week in 2014.
- The General Manager of Omnicare of Southern California testified that the pharmacy filled approximately 120,000 prescriptions each month.
- A dispensing pharmacist who worked from 2011 to 2018 at Omnicare of Dover in Ohio reported that each individual pharmacist was expected to review up to 75 orders per hour, or up to 600 orders during an eight-hour shift.

108. Omnicare pharmacies were woefully understaffed to handle this excessive workload. Pharmacy managers exerted significant pressure on pharmacists and order entry staff to use Omnicare’s computer systems to process prescriptions at an extraordinary pace and get medications out the door quickly. That way Omnicare could bill and collect payments from third party payors, including Government Payors. As a result, staff lacked sufficient time to carefully

review prescriptions, make sure that medications were medically appropriate, assess potential drug interactions, and ensure that dispensations were authorized by a current, valid prescription.

109. Omnicare pharmacists themselves reported the pressure they felt from Omnicare management to get prescriptions out the door. For example:

- A dispensing pharmacist at Omnicare of Golden in Colorado from 2014 to 2017 reported that each pharmacist needed to handle as many as 480 prescriptions each day and that there was tremendous pressure to process an inordinate number of prescriptions each day. She described management as being particularly focused on high volumes of dispensations.
- A former Pharmacist-in-Charge of Omnicare of Wichita who worked there from 2014 to 2017 reported that the pharmacy was consistently understaffed and that employees were under significant pressure to fill prescriptions quickly. The pharmacists responsible for confirming that prescriptions were valid and complete and that drugs were clinically appropriate (*e.g.*, checking for allergies, drug interactions, duplicate therapies, contraindications) were expected to review 60 to 65 orders every hour, or between 480 and 520 orders during an eight-hour shift.
- A dispensing pharmacist at Omnicare of St. Louis from 2011 to 2018 reported that the pharmacy dispensed thousands of medications each day and that she was overwhelmed by the sheer volume. On a given day, the pharmacist was required to review 400 to 600 orders.
- A dispensing pharmacist at Omnicare of Kansas City from 2014 to 2018 reported that some pharmacists blew through the process of reviewing prescriptions due to pressure from headquarters to review an exorbitant number of orders each hour and each day. The pharmacy processed up to 10,000 medication orders each day.
- A dispensing pharmacist at Omnicare of Panama City from 2011 to 2017 who was responsible for confirming that prescriptions were complete and that the drugs were clinically appropriate reported that he was required to review between 500 and 600 orders during an eight-hour shift. The pharmacist referred to a constant backlog of orders.

B. Omnicare Failed To Effectively Train Pharmacy Staff On Core Dispensing Obligations.

110. Omnicare failed to adequately train the thousands of pharmacists, pharmacy technicians, and order entry staff who worked at its pharmacies across the country.

111. Specifically, Omnicare offered little or no training in core areas involving the dispensing of medications to ALFs and other Residential Facilities such as: how to evaluate the validity of prescriptions; how to enter prescription information into the company's computer dispensing systems; how to track the number of authorized prescription refills; how to track prescription expiration dates; and how the requirements for dispensing medications differ between skilled and unskilled facilities. Instead of requiring formal training in these areas, Omnicare left its employees, including order entry staff, pharmacists, and technicians, to try to learn on the job while facing tremendous pressure to process huge volumes of prescriptions.

112. Omnicare's own staff complained about the lack of training. For example:

- A pharmacist who worked for a Louisiana Omnicare pharmacy from 2008 to 2016 reported that new pharmacists were left to sink or swim and that any training materials were not readily accessible. She did not receive adequate training regarding the prescription requirements for ALFs or the proper use and limitations of the computer systems.
- A dispensing pharmacist at Omnicare of St. Louis from 2013 to 2018 described the training he received as very poor. He noted that his peers did not have time to train him and that he was forced to learn the job on his own.
- A dispensing pharmacist who worked at an Omnicare pharmacy in Fort Worth, Texas from 2012 to 2018 reported that there was no standardized training and any training she received was ad hoc. Pharmacists needed to rely on the person sitting next to them to answer questions, resulting in confusion.
- A pharmacist who worked at Omnicare of Cincinnati reported that she was confused by the types of documents she received from facilities and

that Omnicare failed to provide training on what constituted a valid prescription.

113. Importantly, Omnicare provided no standardized training or guidance to pharmacy staff on ensuring that prescriptions for Residential Facilities were tracked and timely renewed. Indeed, a long-time Omnicare employee who consulted with pharmacies across the country testified that she was not aware of any corporate policy or procedure setting forth how pharmacies should seek new prescriptions for ALF residents.

C. Omnicare’s Compliance Program Failed To Ensure That Pharmacies Complied With Core Dispensing Obligations.

114. During much of the Relevant Period, Omnicare’s Compliance Department was understaffed and failed to put in place a program to effectively monitor the operations of Omnicare’s sprawling and rapidly growing network of individual pharmacies.

115. For example, during the early portion of the Relevant Period, Omnicare’s Compliance Department consisted only of a Chief Compliance Officer, his deputy, and a small number of Regional Compliance Officers (“RCOs”) who each were responsible for overseeing pharmacy operations in numerous states across the country. These RCOs had no administrative staff to support them in their compliance role.

116. Moreover, the RCO’s role was narrow. RCOs were not responsible for ensuring that pharmacies complied with specific state pharmacy regulations, and were not even required to be familiar with such regulations. Instead, compliance with applicable laws regarding the dispensing of prescription drugs—the core of Omnicare’s business—was left to the pharmacies themselves. Indeed, when specifically asked whether he had any responsibility for compliance with state pharmacy regulations during testimony provided to the Government, a former

Omnicare RCO indicated that he did not.

117. Furthermore, Omnicare did not conduct regular, comprehensive audits of its pharmacies to ensure that their dispensing practices for non-controlled prescription drugs were consistent with applicable laws. Specifically, the company did not regularly audit pharmacies to determine whether drug dispensations were supported by valid prescriptions.

118. Due, in part, to its ineffective compliance program, Omnicare has been subject to several federal investigations and lawsuits. In particular, in 2012, Omnicare paid \$50 million to settle Department of Justice claims that Omnicare's pharmacies had dispensed controlled substances to long-term care patients across the country without proper prescriptions. Specifically, DOJ claimed that Omnicare routinely and improperly dispensed controlled substances based on facility chart orders, oral orders from facility employees, and other documents instead of requiring a prescription from the prescribing physician. DOJ claimed that Omnicare dispensed controlled substances pursuant to pre-populated prescriptions prepared by pharmacies and pursuant to orders that did not contain all the elements of a valid prescription, including the prescriber's signature. DOJ also claimed that Omnicare did not maintain legally-mandated records of refill prescriptions for Schedule III and IV controlled substances. Omnicare thus has long been aware that dispensing drugs without valid prescriptions violates federal law. Yet, while DOJ's claims and the resulting settlement forced Omnicare to enhance its compliance efforts for controlled substances, the company did little to ensure that its pharmacies complied with prescription requirements for non-controlled drugs.

119. Omnicare has faced numerous other lawsuits and FCA government investigations as a result of its unlawful pharmacy practices. For example:

- In 2006, Omnicare paid \$49.5 million to resolve claims that it had improperly switched Medicaid patients from cheaper versions of three drugs to more costly versions solely to increase the reimbursement rate.
- In 2009, Omnicare paid \$98 million to resolve claims that it had received kickbacks from Johnson & Johnson to recommend Risperdal, an anti-psychotic drug, to long-term care facility patients, and had paid kickbacks to nursing homes to induce them to refer patients to Omnicare.
- In 2014, Omnicare paid \$4.19 million to resolve claims it had received kickbacks from drug manufacturer Amgen Inc. for implementing “therapeutic interchange” programs to switch patients to Amgen’s drug.
- In 2014, Omnicare paid \$124.24 million to resolve claims that it had offered SNFs kickbacks in the form of below-cost contracts to induce the facilities to use Omnicare’s services.
- In 2016, Omnicare paid \$28.1 million to resolve claims that it had received kickbacks from Abbott Laboratories in exchange for promoting Depakote, an anti-epileptic drug, to long-term care patients.
- In 2016, Omnicare paid \$2.24 million to resolve claims that it had manually altered claims submitted to Federal Healthcare Programs to overcome prior rejection of these claims.
- In 2017, Omnicare paid \$8 million to resolve claims that, in order to increase business efficiency and profit, it had implemented an automated label verification system that resulted in in the submission of claims for generic drugs that were different than those actually dispensed to Federal Healthcare Program beneficiaries.
- In 2017, Omnicare paid \$23 million to resolve claims that it had received kickbacks from drug manufacturer Organon USA, Inc. to promote two antidepressant drugs.

120. Omnicare and CVS entered into multiple Corporate Integrity Agreements with HHS’ Office of Inspector General that required them to enhance various aspects of their compliance programs as a result of some of these investigations. Notwithstanding these enforcement actions and scrutiny, Omnicare continued to disregard its fundamental obligation to ensure that it consistently obtained valid authorization prior to dispensing non-controlled

prescription drugs.

V. Omnicare's Computer Systems Allowed Prescriptions To "Roll Over."

121. Omnicare pharmacies use two different computer systems to record and track information on prescriptions and dispensations: OmniDX and Oasis. Approximately 60% of Omnicare pharmacies use the OmniDX dispensing system, while the remainder use the Oasis dispensing system.

122. As discussed below, each system used specific settings to determine whether Omnicare pharmacies would "roll over" prescriptions by automatically generating a new prescription number, a new number of authorized refills, and/or a new prescription date, so that Omnicare could refill the drugs indefinitely without a new prescription from the patient's physician.

A. The Prescription Order Entry Process

123. Upon receipt of a new prescription for an individual living in a Residential Facility, an Omnicare Order Entry Technician was supposed to enter the prescription information into the pharmacy's computer dispensing system, including the drug name, the prescription date, the prescriber name, directions, and dosage information. The Order Entry Technician was also supposed to enter the total prescribed quantity, which could be entered as the total number of pills that could be dispensed over the life of the prescription (*e.g.*, 365 pills), or the number of refills authorized under the prescription (*e.g.*, 11 refills). The information entered determined how many times the prescription should be filled and when the prescription expired. The information entered into Omnicare's computer systems was the basis of what Omnicare submitted to third-party payors when Omnicare sought reimbursement for drugs dispensed.

124. Accurately entering the number of authorized refills or total quantity prescribed was also critical to ensuring that the pharmacy did not dispense more drugs to patients than the treating physician had prescribed.

125. Once the prescription information was entered into Omnicare's computer system, a pharmacist was supposed to review the prescription to confirm that it was valid and that the drug was clinically appropriate for the patient by, among other things, checking for allergies, drug interactions, duplicate therapies, and contraindications. This confirmation process was called Pharmacist Verification 1 or "PV-1." Importantly, after a prescription was entered and the PV-1 process took place, subsequent refills of the drug generally bypassed the PV-1 review process. (A refill could go through the PV-1 process under limited circumstances, such as when a new allergy had been added to the patient's profile since the initial fill or when there was a potential new drug interaction because the patient had started taking a new drug since the initial fill.)

126. When prescriptions "rolled over," however, the dispensing proceeded as a routine refill, bypassing the PV-1 review process.

B. Omnicare Automatically "Rolled Over" Prescriptions In OmniDX Unless The Retirement Field Was Turned On.

127. In OmniDX, the "Retirement" field setting Omnicare assigned to each long-term facility it served determined whether the pharmacy tracked the number of authorized refills and the prescription's expiration date.

128. This Retirement field was meant to indicate whether a long-term care facility was a "retirement" community, such as an ALF that offered limited or no medical care, as opposed to a healthcare facility, such as a SNF. The Retirement field was supposed to be set to "Y" if the

facility was a residential retirement community, and “N” if the facility was a skilled healthcare facility. Indeed, Omnicare’s OmniDX User Guide specifically provided: “If [a] facility is an ALF or retirement home, enter Y; if not enter N.”

129. The Retirement field was the way in which OmniDX distinguished between dispensing to SNFs on the one hand and to ALFs and other unskilled facilities on the other, to reflect the differences in the level of medical care offered at the two different types of facilities, as well as the legal requirement that prescriptions for residential retirement communities must provide for refill or quantity limitations and expire after a certain period.

130. When the Retirement field was turned on (*i.e.*, set to “Y” for a facility), the system required pharmacy staff to manually enter a number in either the “Refills Allowed” field (the total number of refills authorized by the physician) when entering a new non-controlled prescription order into OmniDX. That is, the system would not process the prescription for dispensing unless Omnicare entered a number in either field.

131. Each time the pharmacy filled the prescription, the Refills Allowed field decreased by one. And when the field reached zero, OmniDX would not process additional dispensations. Instead, OmniDX generated a prompt requiring pharmacy staff to obtain a new prescription. In other words, if the Retirement field for a facility was turned on, then OmniDX prevented the pharmacy from “rolling over” prescriptions for residents of that facility.

132. By contrast, if the Retirement field was off (*i.e.*, a facility set to “N” for Retirement), then Omnicare staff were *not required* to enter any number of refills for a new prescription. Instead, the Refills Allowed field auto-populated to an artificially high default number, which, for Medicare Part D patients, was 99 refills. As a result, unless this default refill

entry was manually overridden, Omnicare automatically filled prescriptions up to 99 times without any prompt requiring pharmacy staff to contact the patient's treating physician to determine whether the patient should remain on the drug. And if Omnicare's dispensing reached the artificial default number of refills (which could be lower than 99), Omnicare then allowed the prescription to "roll over," automatically generating a new prescription number and resetting the default number of allowable refills.

133. The OmniDX Retirement field setting also determined whether the system tracked a prescription's expiration date. OmniDX tracked the expiration date based on the date in the "RX Issue Date" field, which typically defaulted to the date the prescription was first filled. If the facility was designated as a retirement community, OmniDX would not process a dispensation after the prescription's expiration. Instead, pharmacy staff automatically received a prompt requiring a new prescription from the prescriber and preventing them from moving forward with dispensing the drug.

134. In contrast, if the Retirement field was off, the prescription "rolled over" after the prescription expired, OmniDX automatically generated a new order number (as if a new prescription had been obtained), and the RX Issue Date field automatically changed to the new fill date for the "rollover" dispensing. Thus, if the Retirement field was off, the system would continue to process drug dispensations after the prescription expired.

C. Omnicare Automatically "Rolled Over" Prescriptions In Oasis Unless The Prescribed Quantity Required Field Was Turned On.

135. In the Oasis system, the "Prescribed Quantity Required" field determined whether the system tracked the total quantity of medication prescribed/authorized refills, or whether prescriptions could "roll over."

136. The Prescribed Quantity Required field was meant to indicate whether a long term care facility was the type of facility where resident prescriptions were required to specify a total quantity of medications prescribed (as is the case with residential Facilities). As a result, the Prescribed Quantity Required field was supposed to be set to “Y” if the prescription came from a resident of an ALF or other Residential community and “N” if the prescription came from a SNF resident.

137. In Oasis, when the Prescribed Quantity Required field was turned on (*i.e.*, set to “Y”), Oasis required pharmacy staff to enter the total prescribed quantity/authorized refills at order entry, and the system would use that number to track the remaining prescribed quantity or refills after each fill. Once that number of refills was exhausted, Oasis prevented any additional dispensations.

138. But when the Prescribed Quantity Required field was off (*i.e.*, set to “N”), the system *did not require* pharmacy staff to enter the prescribed quantity/authorized refills at order entry, and prescriptions “rolled over” if no prescribed quantity was manually entered. When the prescription “rolled over,” Oasis would assign a new order number as if a new prescription had been received, and Omnicare pharmacy staff would dispense the drug indefinitely without receiving notice that they needed to contact the patient’s treating physician to obtain a new prescription.

D. Omnicare’s Cycle Fill System Allowed Prescriptions To “Rollover” In OmniDX.

139. Omnicare filled prescriptions through “demand” dispensing as well as through its “cycle fill” dispensing system. For “demand” dispensing, the pharmacy refills a prescription only upon request from a facility. By contrast, cycle fill dispensations are scheduled to occur on a

regular, pre-determined timetable, at which point the pharmacy refills all drugs for multiple residents of a facility, all on the same day.

140. Most of the facilities that receive medications via the cycle fill program are assisted living communities. Indeed, Omnicare heavily marketed its cycle fill program to prospective ALF clients, representing that it offered an efficient and easy way to refill medications.

141. In OmniDX, during most of the Relevant Period, all prescriptions for drugs dispensed via the cycle fill program were allowed to “roll over” after any authorized refills were exhausted or after the prescriptions expired.

OMNICARE’S FRAUDULENT CONDUCT

I. Omnicare Routinely Dispensed Prescription Drugs To Federal Healthcare Program Beneficiaries Residing In ALFs And Other Residential Facilities Without Current, Valid Prescriptions.

142. During the Relevant Period, Omnicare pharmacies throughout the country routinely dispensed prescription drugs to Federal Healthcare Program beneficiaries residing in ALFs and other Residential Facilities based on stale, invalid prescriptions. Omnicare billed Government Payors for these illegal drug dispensations. Omnicare distributed massive quantities of drugs, blatantly disregarding its basic obligation as a pharmacy to obtain prescriptions for drugs and confirm the patients’ ongoing need for the drugs.

143. Specifically, Omnicare pharmacies knowingly dispensed drugs to individuals living in Residential Facilities month after month based on prescriptions that had expired or had run out of refills, or were not legally valid. As a result, Federal Healthcare Program beneficiaries received prescription drugs for extended periods of time without having their physicians

determine whether it was safe and appropriate for them to continue taking the drugs to treat their conditions.

144. Omnicare pharmacies frequently did not distinguish between assisted living facility residents and skilled nursing facility residents, refilling drugs and allowing prescriptions to “roll over” for residents of any long-term care facility. Despite the well-known fact that unskilled facilities do not typically have doctors to regularly monitor patients’ medications, Omnicare pharmacies regularly failed to ensure that they had current, valid prescriptions before dispensing medications to residents of ALFs. For example:

- A dispensing pharmacist at Omnicare of Golden from 2014 to 2017 reported that the pharmacy did not distinguish between the information required to dispense prescription drugs to SNFs and ALFs, that documentation for both regularly did not specify refill quantities, and that staff just kept renewing prescriptions as long as patients were still active in the facility.
- A former Pharmacist-in-Charge who worked from 2014 to 2017 at Omnicare of Wichita acknowledged that ALFs and SNFs were treated similarly and prescriptions could roll over in the same way for either type of facility.
- A dispensing pharmacist at Omnicare of St. Louis from 2013 to 2018 acknowledged that the pharmacy did not treat SNFs and ALFs differently in terms of what constituted a valid prescription.

145. When Omnicare “rolled over” prescriptions, the pharmacy processed every fill as if it were a routine refill authorized under an existing valid prescription. As a result, the Omnicare pharmacy bypassed the PV-1 review process and drugs were dispensed indefinitely, without having a pharmacist—or a doctor—confirm that the drug was still clinically appropriate, and evaluate potential adverse drug interactions or contraindications.

146. OmniDX and Oasis did not track the number of refills and expiration dates for prescriptions written for tens of thousands of residents living in over 1,700 ALFs and other

Residential Facilities because the computer systems treated them as if they were SNFs.

147. In addition, Omnicare pharmacies using OmniDX regularly refilled medications without valid prescriptions for at least 1,400 additional Residential Facilities that received medications through Omnicare's cycle fill program. The cycle fill medications automatically "rolled over" after authorized refills had been exhausted or the underlying prescription had expired.

148. Further, pharmacy staff dispensed prescription drugs to individuals living in Residential Facilities based on records that did not constitute valid prescriptions from a healthcare provider with prescriptive authority. This was in large part due to Omnicare's failure to properly train staff on the required elements of a valid prescription for ALFs and other Residential Facilities, and specifically the requirement to specify the number of refills/total quantity prescribed. In a rush to process an inordinate number of orders every day, pharmacy staff routinely accepted and relied upon records sent by the Residential Facility that did not meet the legal requirements for a prescription, and had not been approved or issued by a physician. Pharmacy staff improperly entered information into the computer system as if a valid prescription had been received, allowing the dispensing to proceed.

A. Omnicare Disregarded Quantity And Time Limits On Prescriptions, "Rolling Over" Prescriptions For Drugs Distributed To Residents Of Over 3,000 ALFs And Other Residential Facilities.

149. Omnicare did not track the expiration date or number of authorized refills/total prescribed quantity for prescriptions used to dispense drugs to residents of over 3,000 ALFs and other unskilled residential facilities. Omnicare disabled this prescription tracking functionality for these facilities in OmniDX and Oasis so prescriptions "rolled over." As a result, Omnicare

pharmacies dispensed drugs for months, and sometimes years, to elderly and disabled individuals in these residential facilities after the prescription had expired or any refills had been exhausted. There was no valid prescription for these dispensations. These facilities are referred to in this Complaint as “Rollover Residential Facilities.”

150. Given the constant pressure to get prescriptions out the door, Omnicare pharmacists and technicians were forced to rely on Omnicare’s computer systems to track the prescription’s expiration date and refill limits and to alert them that a new prescription was needed. The overburdened pharmacy staff had no time to independently review the underlying records to determine whether there was a current, valid prescription due to the tremendous volume of orders they were expected to process each day.

151. The Rollover Residential Facilities included ALFs operated by the largest long-term care operators in the country, including Brookdale Senior Living, Atria Senior Living, Sunrise Senior Living Services, and Five Star Senior Living.

1. Omnicare Pharmacies Using OmniDX “Rolled Over” Prescriptions For Drugs Dispensed To Residents Of At Least 1,256 ALFs And Other Residential Facilities.

152. During the Relevant Period, Omnicare pharmacies that used OmniDX “rolled over” prescriptions for residents in at least 1,256 ALFs and other Residential Facilities, resulting in drugs being dispensed without a valid prescription for months and sometimes years. These illegal dispensations occurred because Omnicare turned off the Retirement field for these Rollover Residential Facilities, inaccurately designating them as non-retirement facilities in the OmniDX system.

153. Management failed to provide pharmacy staff with sufficient guidance and

training on the import of the Retirement field, as well as the requirement to consistently designate unskilled facilities as retirement facilities.

154. Indeed, there was no standardized process to properly set up facilities in OmniDX. Information on new facilities was entered in an ad hoc, decentralized, and haphazard manner. The responsibility for setting up each facility on the OmniDX system, including whether to classify a facility as a retirement community, was generally left to the discretion of pharmacy employees.

155. Most pharmacists who actually dispensed medications were not even aware of the Retirement field or its import.

156. A list of the names, location, and Omnicare internal identification numbers of 1,256 of the OmniDX Rollover Residential Facilities, as they appeared in OmniDX, is attached as Exhibit 1 to the Complaint.¹ The facilities are located in 33 different states and Washington, D.C. The Omnicare pharmacies that dispensed medications to each of these facilities are also listed in Exhibit 1. According to company data, Omnicare pharmacies dispensed medications to more than 20,000 Medicare beneficiaries and more than 10,000 Medicaid beneficiaries who resided in these 1,256 facilities from January 2012 through April 2016 alone. In addition to these 1,256 facilities, which were specifically identified through data Omnicare produced during the Government's investigation, Omnicare improperly designated other unskilled facilities as non-

¹ Exhibits 1, 2, and 4 reflect the names of facilities and their locations as they appear in the OmniDX and Oasis systems and as they were provided to the Government by Omnicare during the investigation. These names do not necessarily refer to the legal name of the facility, but the identifying information provided should be sufficient to allow Defendants to identify each of the facilities listed in the exhibits. In addition, the names of the listed Omnicare pharmacies may have changed during the Relevant Period.

retirement facilities in OmniDX during the Relevant Period.

157. When a prescription “rolled over” in OmniDX, the “prescription written” date included in the claims data transmitted to Government Payors was false. The claims data was pulled from OmniDX and included a field called “Date_RX_Written.” For “rolled over” prescriptions, the date included in this field would reflect the date the prescription was rolled over and filled. However, no new prescription was actually written or obtained on that date. The false date made it appear to the Government Payor that the drug had been refilled close in time to the “prescription written” date, when in fact the underlying prescription had expired and was no longer valid.

2. Omnicare Pharmacies Using Oasis “Rolled Over” Prescriptions For Drugs Dispensed To Residents Of At Least 510 ALFs And Other Residential Facilities.

158. During the Relevant Period, Omnicare pharmacies that used Oasis “rolled over” prescriptions for residents of at least 510 unskilled facilities, resulting in drugs being dispensed based on stale, invalid prescriptions. These illegal dispensations happened because Omnicare turned off the Prescribed Quantity Required field for these Oasis Rollover Residential Facilities.

159. Pharmacy staff who used Oasis were well aware of this system-wide problem. For example, a former General Manager of Omnicare of La Crosse, a Wisconsin pharmacy, described Oasis as a flawed system that failed to alert staff when there were no refills remaining on ALF prescriptions.

160. Separately, according to a pharmacist who worked at Omnicare of Dover in Ohio, the Oasis system failed to reliably distinguish between skilled and unskilled facilities and that medications for ALF residents were sometimes processed as SNF orders without any refill

limitations. She complained numerous times to pharmacy management about this issue to no avail.

161. A list of the names, locations, and Omnicare internal identification numbers of 510 of the Oasis Rollover Residential Facilities, as they appeared in Oasis, is attached as Exhibit 2 to the Complaint. The facilities are located in 15 different states. The Omnicare pharmacies that dispensed medications to each of these facilities are also listed in Exhibit 2. In addition to these 510 facilities, which were specifically identified through information Omnicare produced during the Government's investigation, there were other unskilled facilities improperly coded in Oasis during the Relevant Period which resulted in prescriptions rolling over and being dispensed without a valid prescription.

3. Through Its Cycle Fill Program, Omnicare Pharmacies "Rolled Over" Prescriptions For Drugs Dispensed To At Least 1,476 ALFs And Other Residential Facilities.

162. As discussed above, many Omnicare pharmacies dispensed prescription drugs through the automated cycle fill system. During the Relevant Period, the pharmacies that used OmniDX routinely dispensed drugs to residents of assisted living and other Residential Facilities after prescriptions for the cycle fill medications had expired or the allotted refills had been exceeded. There were no valid prescriptions for these dispensations. Residential Facilities that received drugs through the cycle fill system from Omnicare pharmacies that used OmniDX are referred to herein as "Cycle Fill Rollover Residential Facilities."

163. OmniDX was set up so that prescriptions for all drugs dispensed via the cycle fill program would *automatically "roll over,"* whether or not the facility was classified as a "retirement" facility in the system. Even when an ALF was designated as a retirement facility so

that OmniDX tracked refills, Omnicare's cycle fill program bypassed the prompts that would have been triggered by an expired prescription and allowed the prescription to "roll over" anyway. Omnicare did this to ensure that pharmacies would keep supplying prescription drugs on a regular schedule, regardless of whether the total prescribed quantity had already been dispensed.

164. OmniDX has a setting that specifically controls whether cycle fill prescriptions can roll over, and Omnicare knowingly programmed this setting to always allow "rollovers." By doing this, Omnicare turned off the automatic halt in the dispensing process that would have occurred when the system detected that a prescription was no longer valid. As a result, pharmacy staff could move forward with processing, labeling, and packaging the large volume of medications to be shipped each cycle (which could take several days), without having to pause to reach out to physicians to obtain new prescriptions.

165. Omnicare pharmacy staff routinely failed to verify that a valid prescription existed for all medications included in the bulk cycle fill shipments delivered to Residential Facilities. Once again, Omnicare prioritized getting medications out the door quickly and maximizing its revenues over ensuring that prescription drugs were only dispensed to elderly residents when legally authorized by a physician or other licensed provider.

166. When a prescription "rolled over," the Refills Allowed field in OmniDX would automatically reset and the RX Issue Date Field would automatically change to reflect the date of the new cycle fill dispensing. In other words, as was the case with "rollovers" generally, the OmniDX entries changed to make it appear that a new prescription had been issued by a physician, when in fact Omnicare did not have a new prescription. As noted above, the false

prescription date was among the data transmitted to Government Payors when Omnicare submitted claims for payment.

167. A list of 74 Omnicare pharmacies that used the OmniDX system and dispensed medications via the cycle fill system to individuals in Residential Facilities during the Relevant Period is attached as Exhibit 3 to the Complaint. According to company data, these 74 Omnicare pharmacies dispensed drugs via the cycle program to over 28,000 Medicare beneficiaries and over 4,700 Medicaid beneficiaries who resided in facilities located in 30 states and Washington, D.C. designated as residential retirement facilities in OmniDX. A list of the names, locations, and Omnicare internal identification numbers of 1,476 facilities that were classified as unskilled facilities in the OmniDX system and received cycle fill shipments for Medicare and Medicaid beneficiaries is attached as Exhibit 4.

168. Omnicare managers and compliance personnel knew that the cycle fill system continued to process refill orders month after month long after prescriptions had expired. For example, in an internal email, an Omnicare compliance manager described the cycle fill process as follows: “The DX System would allow refills to ‘roll-over’ if they ran out of refills. I’m not sure how this would ever be deemed an acceptable practice in a true ALF setting They need new scripts.”

169. In addition, in an internal email exchange concerning a cycle fill dispensing for an assisted living resident, a supervisor at Omnicare of Chandler, an Arizona pharmacy, advised an employee who was gathering records in response to an audit: “The only request from the facility will be the initial new order for a particular medication and this will be sent to get the resident enough days to cycle fill. Then once the cycle is due, the med will be automatically refilled each

month until someone from the facility [discontinues] the med.” This email was forwarded to an Omnicare Regional Compliance Officer with the message “SYK,” which presumably stood for “so you know.”

170. Omnicare also frequently delivered cycle fill shipments to Cycle Fill Rollover Residential Facilities without any confirmation from the facility that the residents were out of the medication and needed the next fill, or were even still taking the same medication.

171. Under Omnicare’s written policies, prior to each periodic cycle fill delivery, facility staff were supposed to review a report sent from the Omnicare pharmacy listing the medications the pharmacy intended to dispense. The facility was supposed to make any necessary changes and return a signed authorization form to the pharmacy. As stated in Omnicare’s Cycle Fill Policy and Procedures, the form “gives the pharmacy permission to refill all cycle fill medications. Without this form the pharmacy does not have permission and should not dispense any cycle fill medications without obtaining authorization.”

172. However, many Omnicare pharmacies, including but not limited to Omnicare of Salt Lake City, Omnicare of Nashville, Omnicare of Minnesota, Omnicare of Southern California, Omnicare of Northern Massachusetts, Omnicare of King of Prussia, and an Omnicare pharmacy located in Newport, Pennsylvania, frequently delivered cycle fill shipments without first receiving authorization forms from facilities.

173. The failure of pharmacies to consistently obtain the authorization forms was well-documented through internal audits and assessments. For example, a 2013 Omnicare internal audit looked at the cycle fill procedures for ten facilities served by Omnicare of Southern California and concluded that “[a]ll 10 facilities did not have a signed authorization on file to

support the cycle fill. The current pharmacy cycle fill process does not entail obtaining authorizations to refill from customers or facilities. Rather, the pharmacy relies on facility returns and refusals to determine which medications are not needed.” The audit report was circulated to various Omnicare compliance personnel, including the Chief Compliance Officer. Later, in 2017, CVS’s audit team conducted an audit of Omnicare’s “Revenue Process” that also identified instances where the signed cycle fill authorization form had not been obtained by pharmacies. CVS’s Vice President and Chief Audit Executive directed management to “design and implement a monitoring program to assess pharmacy compliance with required refill authorizations.”

B. Omnicare Dispensed Prescription Drugs To Residents Of ALFs And Other Residential Facilities Based On Records That Did Not Constitute Valid Prescriptions.

174. When dispensing prescription drugs to Federal Healthcare Program beneficiaries at Rollover Residential Facilities, Omnicare relied on records that were not valid prescriptions from healthcare providers with prescriptive authority. Omnicare failed to adequately train pharmacy staff on the requirements of a valid prescription for drugs dispensed to residents of ALFs and other non-skilled facilities, including the requirement that the prescription specify the total quantity prescribed/number of refills. As discussed above, pharmacy data entry staff were not required to record any refill or quantity limitation when entering prescriptions for OmniDX and Oasis Rollover Residential Facilities.

175. Facing tremendous pressure to quickly enter and process a huge number of drug orders, pharmacy staff routinely accepted and relied upon documents that were not legitimate prescriptions, entering information into the OmniDX or Oasis systems as if a valid prescription

had been received. Once a “prescription” was entered, the pharmacy could continuously refill it. The prescription “rolled over” and there was no system in place to go back and verify that a lawful prescription had ever been obtained.

176. Omnicare did not provide clear guidance to pharmacy staff on what constituted lawful prescriptions for ALF residents under applicable state law.

177. Indeed, a former Omnicare Regional Compliance Officer testified that he was not aware of any training that Omnicare provided in his region concerning the differences between the required documentation for dispensing medications to residents of non-skilled facilities as compared to residents of skilled facilities.

178. Former Omnicare staff complained about the lack of training and the confusion it caused. For instance:

- A dispensing pharmacist who worked from 2012 to 2018 at an Omnicare pharmacy in Fort Worth, Texas recalled constantly inquiring as to whether the orders provided constituted valid prescriptions for ALF residents but received little guidance.
- A pharmacist who began working at Omnicare of St. Louis in 2011 acknowledged that she and her colleagues were not aware of the different rules for dispensing medications to ALFs and SNFs, including the refill limitation requirement, until several years after she started working at the pharmacy.
- A pharmacist who worked at Omnicare of Cincinnati in 2016 noted that she was confused by the documents she received from facilities and there was no training on what constituted a valid prescription.
- A dispensing pharmacist who worked at Omnicare of Wichita from 2015 to 2017 confirmed that she and the other pharmacists did not receive any training from Omnicare on what constituted a valid prescription for ALF residents.
- A former triage technician who handled order entry at Omnicare of Salt Lake City asked for guidelines concerning the requirements for a SNF and

ALF prescription but was told no such guidelines existed.

179. Omnicare pharmacies improperly accepted and dispensed medications based upon a wide range of records provided by Rollover Residential Facilities that did not constitute legally valid prescriptions. Omnicare's overwhelmed and poorly trained pharmacy staff treated these documents, which were not generated by a physician, as if they were valid prescriptions, and entered information into the computer system to trigger the dispensing process.

180. For example, pharmacies improperly filled medications based solely on receipt of a resident's Medical Administration Record ("MAR") from the Residential Facility. A MAR is designed to reflect and track the drugs administered to residents at a long-term facility. However, the MAR itself is not a valid prescription and is typically not approved or signed by a healthcare provider with prescriptive authority in a Residential Facility.

181. In addition, Residential Facilities often sent Omnicare pharmacies copies of medication lists/reports from the hospital or other healthcare facility where residents had stayed prior to their admission into their current facility. Facility staff typically received these lists/reports as part of the admissions process. These lists/reports, which may have reflected the drugs the resident had been taking when discharged from his or her prior facility, are not valid prescriptions. They typically do not include the elements of a valid prescription, do not authorize future refills, and are often not approved or signed by a physician. Nonetheless, Omnicare pharmacies relied on these lists/reports to repeatedly dispense drugs.

182. Omnicare pharmacies also improperly relied on faxes or verbal refill requests from Residential Facility staff to refill medications when there was no valid underlying prescription authorizing the fill. These faxes and verbal requests were not from authorized

prescribers and did not constitute valid prescriptions.

183. As another example, Omnicare pharmacies improperly relied upon prescriptions that had not been signed by any physician or other authorized prescriber, or their agents.

184. Notably, in the context of Medicare Part D PDE validation audits, CMS does not accept MARs, outdated hospital discharge records, faxed refill requests from unskilled facilities, or unsigned prescriptions as support for the validity of Part D claims. This is because these documents are not valid prescriptions and render the underlying claim ineligible for payment.

II. Defendants Knew That Omnicare Pharmacies Routinely “Rolled Over” Prescriptions And Dispensed Drugs To Residents Of ALFs And Other Residential Facilities Without Current, Valid Prescriptions, But Did Not Address The Problem Until After They Became Aware Of The Government’s Investigation.

185. Senior Omnicare Operations and Compliance managers recognized the limited medical care provided at Residential Facilities, and understood that valid prescriptions that specified authorized refills or total prescribed quantities were required in order to continue to dispense drugs to residents of ALFs and other Residential Facilities. Yet, throughout the Relevant Period, Omnicare managers learned that Omnicare pharmacies were “rolling over” prescriptions and routinely dispensing drugs to elderly individuals living in Residential Facilities without valid prescriptions that met those requirements.

186. In addition, shortly after CVS acquired Omnicare in May 2015, CVS managers became aware that Omnicare pharmacies were “rolling over” prescriptions without valid authorization. After the acquisition, CVS assumed control over Omnicare’s Operations and Compliance departments, overseeing Omnicare pharmacy dispensing practices, policies, and systems. CVS was notified that Omnicare pharmacies were dispensing drugs to residents of ALFs and other Residential Facilities without valid prescriptions. And CVS discussed the

specific “rollover” problem with senior Omnicare operations managers.

187. Despite this, neither Omnicare nor CVS addressed the problem until after they became aware of the Government’s investigation.

A. Omnicare And CVS Understood That Omnicare Needed Current Prescriptions With Authorized Refills To Continue To Dispense Drugs To Residents Of ALFs And Other Residential Facilities.

188. Defendants understood the difference between skilled and Residential Facilities, and the different level of medical care provided at each. Although Omnicare could arguably continuously dispense drugs based on chart orders regularly available in the hospital-like setting of SNFs, the company recognized that it needed valid current prescriptions to dispense drugs to Residential Facilities.

189. As a Omnicare Regional Compliance Officer explained, “in skilled, the nurses will transmit to the pharmacy chart orders from the prescriber, and so the facility is providing the orders as in a hospital.” On the other hand, “[i]n assisted living, that resident is living [in] their home, so their prescriptions come from the prescriber. So the patient might see the doctor and bring it back with them, and then a caregiver might send it over to the pharmacy or the physician just directly sends a prescription to the pharmacy.”

190. Omnicare employees discussed the differences between skilled and unskilled facilities, and the importance of having valid prescriptions with authorized refills to dispense drugs to residents of unskilled facilities.

191. For example, in February 2012, a nurse working in an Omnicare pharmacy in Illinois asked the Omnicare Compliance Department what type of documentation would be considered valid authorization to dispense in a Residential Facility “that doesn’t have a nurse in

house 24/7.” In response, an Omnicare Compliance employee informed her that “[i]n most states, assisted living and [facilities for the developmentally disabled] are considered retail so the retail rules would apply. In order for it to be a valid script, it would need to contain all the required elements. Patient and physician info, drug info, *including qty and refills*.” (Emphasis added.)

192. In June 2012, Omnicare’s Director of Customer Service for the West Division asked whether Omnicare could dispense medications based on an ALF resident’s Omnicare Resident Profile, which included a list of prescription drugs the resident was taking at the time. In response, an Omnicare Regional Compliance Officer responded that “[m]ost states treat ALF as a residence, and so actual prescriptions need to be issued prior to dispensing.”

193. In June 2013, a manager in Omnicare’s Medicare billing department asked whether an Omnicare pharmacy in Ohio needed “to have a prescriber-signed order for drugs being dispensed to residents in independent/assisted living type communities.” The pharmacy manager noted her view that signed prescription orders *were* required because Residential Facilities did not regularly have such orders for residents, “whereas in skilled settings there should be a signed [Physician Order Sheet] every month to fall back on if need be.” An Omnicare Compliance Officer responded: “yes, I agree with you that for less than Skilled, we treat them like Retail and require signed prescriptions.”

194. Similarly, in October 2013, the Pharmacy Director of an Omnicare pharmacy in Louisiana noted that a Louisiana Board of Pharmacy inspector had “asked about Rx’s rolling over,” and “wanted to know how many times an Rx can roll with the same Rx number.” An Omnicare Regional Compliance Officer responded that the “rule of thumb is no less than annually should a new Rx or authorization be obtained for ALF, and for SNF we try to get

documentation for annual approval, but the Rx # can remain the same.”

195. And in December 2015, Omnicare’s Business Capabilities Architect sent an email to operations managers at Omnicare and CVS regarding proposed changes to OmniDX and Oasis to account for the fact that “[i]n the ALF and independent living setting we need to ‘renew’ prescriptions by contacting the doctor for a new RX once the existing RX is out of refills or remaining quantity,” while “[i]n a SNF setting most of this renewal practice is accomplished seamlessly using signed physician order sheets or certified medication ordering systems.”

B. Omnicare And CVS Knew That Omnicare Pharmacies Routinely “Rolled Over” Prescriptions And Dispensed Drugs To Residents Of ALFs And Other Residential Facilities Without Current, Valid Prescriptions.

196. Throughout the Relevant Period, Omnicare management knew that pharmacies across the country routinely dispensed prescription drugs to Residential Facilities without valid authorization. Omnicare Operations and Compliance managers were alerted to the problem through: (1) State Board of Pharmacy findings that Omnicare dispensed prescription drugs beyond what prescriptions authorized; (2) third-party audits showing that pharmacies regularly lacked documentation to justify dispensations; (3) internal audits showing that pharmacies dispensed drugs without valid prescriptions; (4) complaints from Omnicare pharmacies that Omnicare’s systems dispensed prescription drugs without valid authorizations; and (5) complaints from unskilled facilities that Omnicare was dispensing medications after refills had been exhausted.

1. State Boards Of Pharmacy Alerted Omnicare And CVS That Omnicare Pharmacies Dispensed Drugs Without Valid Prescriptions.

197. During the Relevant Period, several state regulatory agencies found that Omnicare pharmacies dispensed prescription drugs without valid authorization in violation of applicable

state pharmacy law. For example:

198. *Utah Division of Occupational and Professional Licensing*. After conducting an on-site inspection of Omnicare of Salt Lake City in August 2012, the Utah Division of Occupational and Professional Licensing found, among other things, that the pharmacy “dispensed or otherwise distributed legend drugs beyond a year from the original order date” without obtaining a new order. Pursuant to a stipulation executed in July 2014, the pharmacy agreed to “receive a corporate-wide pharmacy computer systems update in which systems will automatically discontinue activity on prescriptions for non-controlled substances after one year.” However, the Salt Lake City pharmacy, which used OmniDX, did not change the Retirement field for the facilities it served to stop rollovers until late 2016.

199. *Missouri Board of Pharmacy*. In March 2014, the Missouri Board of Pharmacy issued a Letter of Warning to Omnicare of St. Louis concluding that the pharmacy’s dispensations of prescription drugs under the cycle fill program “were assigned a new prescription number and automatically dispensed without final verification by a pharmacist.”

200. *Ohio Board of Pharmacy*. After receiving a complaint from a prescriber in 2014, the Ohio Board of Pharmacy found that Omnicare of Cincinnati was dispensing prescription medications without the required prescriber authorization, including Prednisone, a steroid that can be dangerous if taken for prolonged periods. After discussing the issue with other Omnicare pharmacies, the head pharmacist of Omnicare of Cincinnati requested that OmniDX be modified to prevent prescriptions from “rolling over” when the prescribed quantity is exhausted. A Regional Compliance Officer circulated the pharmacist’s request and asked Omnicare IT and Operations managers to prioritize solving the problem, emphasizing “the importance of this IT

project” since “it affects all DX pharmacies at a minimum.”

201. *New Mexico Board of Pharmacy*. In 2015, the New Mexico Board of Pharmacy conducted an investigation into the dispensation practices of Omnicare of Albuquerque to residents of assisted living facilities. Since CVS had recently acquired Omnicare, CVS compliance staff were involved in responding to the investigations. The Board ultimately issued a letter finding that “due to a glitch in the cycle fill system, medications were being dispensed after refills had run out” and that “prescription medications were being dispensed pursuant to drug orders which did not have quantities, refills, and in some cases a prescriber’s signature.” The Board stated that its “findings show serious violations of the New Mexico Board of Pharmacy’s statutes and regulations requiring retail pharmacies to dispense medications only pursuant to prescriptions which contain all of the elements of a prescription.” The Board’s findings were provided to CVS’s counsel and its Director of Pharmacy Regulatory Affairs. Indeed, CVS Regulatory Affairs representatives discussed the findings with representatives of the Board. Thus, senior CVS managers became well aware of the “rollover” problem shortly after acquiring Omnicare.

2. Third-Party Audits Of Omnicare Pharmacies Found That Omnicare Dispensed Drugs Without Valid Prescriptions.

202. During the Relevant Period, insurance plans, including Medicare Part D sponsors, conducted audits to determine whether claims submitted by Omnicare were supported by valid prescriptions. Numerous such audits found high rates of Omnicare dispensations without valid authorizations. Audit reports frequently found that prescriptions were missing or that the records provided by the pharmacy did not constitute valid prescriptions. Omnicare Operations and Compliance managers were copied on the audit findings. For example:

203. *Omnicare of Minnesota.* An audit conducted in April 2012 found an overpayment of \$146,578.99. Most of the rejected dispensations involved cycle fill dispensations for which the documentation submitted was more than a year old. Omnicare appealed the audit. After another audit in September 2013, the Minnesota pharmacy was placed on a corrective action plan to address its failure to provide a significant percentage of the requested documentation to support the dispensations. The same insurance plan conducted a second follow-up audit in May 2014 and found that Omnicare “submitted 22% of claims beyond the prescription’s expiration date or without obtaining and documenting appropriate authorization from the prescriber for additional refills;” and “failed to provide valid, signed Physician’s Orders for 10% of the claims requested.”

204. *Omnicare of Albuquerque.* An audit focusing on Medicare Part D claims from August 2014 until August 2015 found deficiencies in 54 out of 99 drug dispensations reviewed, resulting in a Part D overpayment of \$13,080.91. Most claims were rejected because the “[p]harmacy did not provide the prescription order.” Thereafter, the pharmacy was placed on a corrective action plan designed to address the deficiencies found. Earlier audits of the Albuquerque Omnicare pharmacy dating back to at least 2012 also identified numerous missing or invalid prescriptions, including a 2014 audit that preliminarily found a \$72,788.61 overpayment based almost entirely on the failure to produce prescriptions.

205. *Omnicare of Spartanburg.* An audit conducted in August 2012 found an overpayment of \$94,466.20, all based on Omnicare’s failure to produce valid prescriptions authorizing dispensations. Omnicare appealed the audit.

206. *Omnicare of Atlanta.* An audit conducted in July 2015 found that the Omnicare pharmacy “failed to provide valid, signed Physician Orders for 43% of the claims requested in

the sample.” Thereafter, the pharmacy was placed on a corrective action plan.

207. *Omnicare of Nacogdoches*. An audit conducted in December 2015 found that the Texas Omnicare pharmacy “failed to provide valid, signed Physician Orders for 52% of the claims requested in the sample.” Thereafter, the pharmacy was placed on a corrective action plan.

3. Omnicare’s Internal Audits Showed That Its Pharmacies Dispensed Drugs Without Valid Prescriptions.

208. As noted above, Omnicare’s Compliance Department failed to conduct regular, comprehensive audits of all of its pharmacies to assess whether non-controlled drug dispensations were justified by valid prescriptions. However, even some of the few internal audits conducted during the early part of the Relevant Period identified this problem.

209. For example, an August 2012 internal operational audit of a South Carolina Omnicare pharmacy found that “[r]enewal physician orders are not consistently obtained due to the lack of an automated process to prevent the pharmacy from dispensing an order beyond 12 months.” In the draft Audit Report, the Omnicare auditors noted that the failure to obtain renewal orders after 12 months was a “common issue[] in this and other similar operational audits in 2012.” The draft report was circulated to several Omnicare compliance managers, including Omnicare’s Chief Compliance Officer.

210. Similarly, a 2012 internal audit of a Pennsylvania Omnicare pharmacy found that “physician orders could not be located,” “orders for patients residing in nursing facilities had not been renewed in over one year,” and “signed facility authorizations” were not obtained prior to dispensing cycle fill orders. A subsequent review conducted in 2013 concluded that the problem of dispensing prescription drugs without authorization persisted.

211. An Audit Services memorandum regarding Omnicare's "Follow-Up Review" of the same Pennsylvania pharmacy referred to the issue of "[p]rescriptions older than one year" as "a corporate-wide issue." Omnicare's Chief Audit Officer forwarded the results of the "Follow-Up Review" to the Chief Compliance Officer.

4. Omnicare Pharmacy Staff Alerted Management That Omnicare's Computer Systems "Rolled Over" Prescriptions For Drugs Dispensed To Residents Of ALFs And Other Residential Facilities.

212. Omnicare's own pharmacies alerted management that OmniDX and Oasis lacked basic controls to reliably prevent Omnicare from dispensing medications that were not authorized by valid prescriptions.

213. For example, an Omnicare pharmacist who worked in Ohio from 2011 until 2018 repeatedly complained to pharmacy managers that ALFs were being set up incorrectly in the Oasis system, causing problems tracking refills for medications for ALF residents. The former Omnicare pharmacist also reported that other Omnicare pharmacies had complained that ALFs were set up incorrectly so Oasis did not track prescription refills. However, the Ohio pharmacists' complaints went unanswered for years.

214. In October 2015, a Maryland pharmacy manger complained that his staff was "finding that refills [for ALF residents] are going through without available refills and the [internal prescription number] is changed." The pharmacy manager gave as an example an ALF resident with a prescription for medication for glaucoma and hypertension in the eye "with zero refills." She noted that "[t]he facility attempted a refill and the refill went through but generated a new [prescription number]." She added, "This is an ALF facility and orders should not automatically refill until there are available refills." In response, the Senior Manager in the

Operations Department noted that pharmacies are “not supposed to allow rollovers for ALF or any type of ‘community’ setting.” When she learned that “the entire facility is setup not to require refills,” the Senior Manager wrote: “*I imagine the scope of this is huge.*” (Emphasis added.)

5. Residential Facilities Alerted Omnicare That Its Pharmacies Dispensed Drugs Without Valid Prescriptions.

215. The staff of Residential Facilities also complained to Omnicare about its problematic dispensing practices.

216. For example, in May 2013, an assisted living facility in Texas alerted Omnicare (and the Texas State Board of Pharmacy) that its Texas pharmacy had dispensed a resident’s Alzheimer’s medication and gastroesophageal disease medication without a valid prescription. In an email, the pharmacy manager informed Omnicare’s Vice President of Operations and Omnicare’s Regional Compliance Officer that the pharmacy had received a complaint that Omnicare had “filled (refilled) the prescriptions 4 or 5 times even though the original prescriptions from the doctors clearly stated NO REFILLS.” Omnicare’s Vice President of Operations responded, noting that the ALF had notified Omnicare about the issue more than two months earlier but there was “no mention or knowledge of board [of pharmacy] involvement.” Omnicare’s Regional Compliance Officer wrote back: “yes, *this will not be pretty.*” (Emphasis added.)

217. And in October 2015, an assisted living facility in Pennsylvania complained that its staff was confused by a prescription label showing 99 refills remaining, while Omnicare’s client computer portal showed zero remaining refills. After the Omnicare pharmacy General Manager “escalated” the issue, Omnicare Operations and IT managers determined that the

facility had been designated as a non-retirement facility in OmniDX, so the number of allowable refills was artificially set to 99. A senior IT manager explained: “an ALF facility should be processing hard-copy scripts, which would suggest changing the [Retirement setting] configuration flag from ‘N’ to ‘Y’ in DX,” as that “would allow for users in DX to be prompted to enter the number of refills for a particular order.”

218. In late February 2016, an assisted living facility in Utah complained when it learned that, every month, Omnicare of Salt Lake City was dispensing approximately 200 drugs using the cycle fill program even though the prescriptions for the 200 drugs had expired. When a pharmacy technician asked how this happened, his supervisor acknowledged that Omnicare’s computer systems did not track prescription expiration dates, and instead “rolled over” prescriptions so the pharmacy could continue dispensing. The pharmacy technician suggested querying the OmniDX system to identify other prescriptions that were being filled based on stale prescriptions, but pharmacy management refused to do so.

C. CVS And Omnicare Operations And Compliance Managers Discussed Omnicare’s Practice Of “Rolling Over” Prescriptions For Drugs Dispensed To Residents Of ALFs And Other Residential Facilities.

219. Given the complaints and findings from multiple sources alerting Omnicare management about its problematic dispensing practices, it is unsurprising that CVS and Omnicare Operations and Compliance managers discussed among themselves that Omnicare pharmacies were routinely “rolling over” prescriptions.

220. For example, in July 2012, senior Omnicare Operations management was informed that Omnicare’s cycle fill program bypassed computer safeguards required to ensure that Omnicare obtained valid prescriptions before dispensing drugs to ALF residents, and that

there was a fix that was not being implemented. In an email exchange, a long-time Omnicare IT employee advised two Omnicare compliance officers: “[C]ycle fill will roll orders,” but “[t]here is a setting that will prevent all . . . ALF orders from rolling.” The IT employee added, however, that a North Carolina pharmacy decided against using the OmniDX setting “because they didn’t want to block ALF orders” from rolling over. This exchange was forwarded to Omnicare’s Senior Director of Operations, who acknowledged the problem, observing: “All retail (think ALF...) . . . must follow ‘retail’ rx rules – actual # of refills and no rolling of the rx number.” Despite this exchange, as discussed below, Omnicare did not implement the setting to prevent cycle fill “rollovers” until more than three years later, after Omnicare learned of the Government’s investigation.

221. And in December 2014, Omnicare Operations managers exchanged emails regarding thousands of cycle fill prescription medications dispensed without valid authorization at Omnicare’s Sacramento pharmacy (which served many assisted living facilities during the Relevant Period). After Omnicare had tried to implement a computer change at that pharmacy “to prevent orders from filling that were either too old, were out of refills, or did not have sufficient quantity to fill,” the pharmacy reported that it had “thousands of orders like this that they are trying to fill today but can’t.” An Operations Manager noted, “Wow... this is not good. Chances are, *they’ve been filling them without the correct number of refills all along and now it’s a big problem.*” (Emphasis added.) She suggested that “we back out the change for now to get the orders filled.” Omnicare’s Senior Director of Operations forwarded the email exchange to the Regional Compliance Officer for the West Division.

222. Indeed, the problem of Omnicare’s computer systems routinely processing drug

dispensations without valid authorization was specifically discussed among all Omnicare Regional Compliance Officers in April 2015, as they were compiling a list of “compliance related IT projects” to send to Omnicare’s Chief Compliance Officer. In an email exchange, one Regional Compliance Officer stated: “An issue that I am running into more and more in multiple states concerns the ability of our systems to allow prescriptions to continue to roll after a year to a new prescription number without any documentation or pharmacist intervention.” Another Compliance Officer then forwarded the email to the head of Omnicare’s Third Party Audit Group, who responded that she had a “potential solution (programmed last year) but no one is rolling it out now.” In fact, Omnicare would not “roll out” a solution until more than one year after that email exchange.

223. The yet-unresolved problem came up again in October 2015, when Omnicare’s Senior Director of Operations circulated a list of “OPS and Compliance Priorities.” The list of priorities set forth the need to modify Oasis to ensure that “orders assigned to assisted living (ALF) patients” did not roll over “[w]hen refilling an order that has reached the RX # expiration days.”

224. Still later, in a February 2016 draft sales memorandum sent to Omnicare and CVS operations managers to identify “Rx Renewal Improvements Supporting ALF Growth,” Omnicare management again acknowledged that “both OmniDX and OASIS have significant gaps in automatically detecting and reviewing expiring [prescriptions] in the variety of processing areas where the last fill can be detected.”

225. Furthermore, an Omnicare Operations manager who consulted with Omnicare pharmacies across the country testified that from 2006 until 2016, she identified numerous

pharmacies that allowed prescriptions for seniors in Residential Facilities to “roll over,” and each time, she advised the pharmacy’s General Manager and her supervisor.

D. Despite Defendants’ Awareness Of Omnicare’s Illegal Dispensing Practices, Defendants Did Not Address The System-Wide “Rollover” Problem Until After The Government’s Investigation Began.

226. Omnicare and CVS finally began to address Omnicare’s illegal practice of routinely dispensing prescription drugs without valid authorization to individuals in ALFs and other Residential Facilities after they became aware of the Government’s investigation.

227. Starting in late 2015 and continuing into 2016, Defendants finally initiated a process to change the Retirement field entries for hundreds of Residential Facilities from “N” to “Y,” so pharmacies could begin tracking prescription refills and expiration dates for medications dispensed to these facilities. As one senior Omnicare Operations manager later put it, the company finally “turned off” “rollovers” in all assisted living facilities.

228. Later, in December 2016, Omnicare altered the OmniDX facility set-up process so that if a facility was unskilled, the Retirement field would automatically default to “Y.” Omnicare also significantly increased its oversight of the process for entering and coding facilities in OmniDX, including by having its corporate Operations team review and verify the accuracy of facility-related information entered into OmniDX by individual pharmacy staff.

229. In May 2016, Omnicare finally changed the control setting in OmniDX to prevent cycle fill medications from “rolling over” for retirement facilities. At the same time, the company substantially revised its cycle fill policy to provide that “rollover” prescriptions would no longer be allowed for ALFs and other unskilled facilities. In response to the announcement of the new policy, a Regional Compliance Officer noted in an internal email that the “requirement

for scripts for [ALFs] . . . would certainly be a major change I would like to start gearing Pharmacies up for.” Another Omnicare employee responded to the policy change: “This is pretty impactful to our business — not even 30 days to implement and notify facilities?”

230. Notwithstanding Omnicare’s awareness for years that expired prescriptions had been “rolling over,” and that Omnicare and CVS had begun in 2015 to address the OmniDX “rollover” problem, Defendants did not take steps to address the almost identical “rollover” problem in the Oasis system for more than two years. Indeed, in a September 2017 email, CVS’s Senior Director of Internal Operations LTC sent an internal email to an IT Director that asked “[w]hat will it take to repeat the process” of preventing ALF rollovers for Oasis.

231. However, nothing was done to address the Oasis “rollover” problem until early 2018 when an Illinois Omnicare pharmacy raised concerns. In response to the concerns, Omnicare conducted a survey of all Oasis pharmacies to determine how often unskilled facilities were set up correctly according to state regulations governing prescriptions for unskilled facilities. A January 2018 email describing the internal review reported that “[a]udits have identified facility set up issues which are allowing orders to continue in perpetuity.”

232. Based on the responses provided by Omnicare’s own pharmacists, Defendants concluded in early 2018 that the 510 unskilled facilities listed in Exhibit 3 had been set up in the Oasis system so that the Prescribed Quantity Required field was “N.” In other words, Omnicare’s own head pharmacists acknowledged that its computerized dispensing system — upon which they had to rely to track the hundreds of thousands of prescriptions drugs dispensed on a daily basis — was set up to not track refills/total prescribed quantity for hundreds of Residential Facilities, thereby allowing prescriptions to be refilled “in perpetuity.”

233. Defendants made these changes because they knew that Omnicare pharmacies had been dispensing prescription drugs to individuals in Residential Facilities, including tens of thousands of Federal Healthcare Program beneficiaries, based on expired or otherwise invalid prescriptions. Defendants also knew, or would have known through the exercise of reasonable due diligence, that they had received tens of millions of dollars in Federal Healthcare Program payments for dispensing these drugs without valid prescriptions. These payments constituted overpayments from Federal Healthcare Programs, and Defendants had an obligation to report and return the identified overpayments. But Defendants did not make any effort to return these payments, or to report to the Government Healthcare Programs, including Part D sponsors, that they had received payments for drugs dispensed without valid authorization. Nor did Defendants take steps to investigate or quantify the overpayment resulting from dispensing prescription drugs to individuals in Residential Facilities without valid authorization.

III. Omnicare Put At Risk The Health Of Elderly And Disabled Residents Of ALFs And Other Residential Facilities By Routinely Dispensing Prescription Drugs To Them Without Valid Prescriptions.

234. Omnicare's illegal practice of dispensing drugs to individuals in ALFs and other Residential Facilities based on expired or otherwise invalid prescriptions exposed these individuals to a significant risk of harm.

235. Prescriptions are required to obtain certain drugs because such drugs can only be taken safely under the supervision of a physician or other licensed prescriber. Physicians are tasked with ensuring that a particular drug or combination of drugs is—and continues to be—a safe, appropriate, and effective means of treating the patient. Indeed, physician oversight of drug treatment is critical for elderly patients, who often suffer from multiple chronic conditions that

require treatment using numerous prescription drugs, and who are particularly vulnerable to side effects and adverse drug events.

236. As Omnicare has repeatedly acknowledged, unskilled facilities like ALFs typically do not have physicians on staff to regularly monitor residents' drug treatment. Thus, for seniors in ALFs, a prescription's expiration or the exhaustion of refills serves as an important trigger for a patient to consult with his or her physician concerning whether the medication should be discontinued or whether the dosage or frequency need to be changed. Without such regular monitoring, an elderly patient's continued use of prescription drugs carries significant risks to the patient's health.

237. Many of the prescription drugs dispensed by Omnicare without valid prescriptions treat serious health conditions, including dementia, hypertension, and diabetes. The drugs used to treat these conditions in elderly patients typically require close monitoring by a physician, sometimes as often as every three to six months.

- Omnicare frequently dispensed antipsychotic medications, such as Risperidone, Quetiapine, and Clozapine, without valid prescriptions. Elderly patients face an increased risk of serious adverse events from antipsychotic medications due to the large number of medications they often take and their lower metabolism rate. Metabolic side effects need to be particularly closely monitored for elderly patients on antipsychotic medications.
- Omnicare also frequently dispensed antidiabetic medications, including Metformin, Glipizide, and Sitagliptin, without valid prescriptions. It is particularly challenging to treat elderly patients with diabetes due to their comorbidities, cognitive disorders, physical disabilities, and higher risk of hypoglycemia. In addition, older patients' use of antidiabetic medications needs to be closely monitored because there is a greater risk that these medications could cause abnormally low blood sugar levels resulting in difficulty walking and falls.
- And Omnicare frequently dispensed cardiovascular medications, such as Lisinopril, Amlodipine, and Losartan, without valid prescriptions. Cardiovascular drugs are known as a class of drugs frequently associated with preventable adverse drug events.

These medications must be carefully monitored when taken by elderly patients. Physicians often need to adjust the dosage and frequency based on the patient's condition and response to the drug. Particularly close monitoring is required for elderly patients with renal impairments.

IV. Omnicare's Illegal Practice Of "Rolling Over" Prescriptions And Dispensing Drugs Without Current, Valid Authorization Resulted In The Submission Of Hundreds Of Thousands Of False Claims To Federal Healthcare Programs.

238. By routinely dispensing prescription drugs to Federal Healthcare Program beneficiaries residing in ALFs and other Residential Facilities without valid prescriptions, Omnicare presented, or caused to be presented, hundreds of thousands of false claims to Federal Healthcare Programs during the Relevant Period. Such claims were ineligible for reimbursement because there was no valid prescription or other authorization to dispense the drug. In addition, Omnicare knowingly transmitted false information to Government Payors that made it appear that the drugs were being dispensed pursuant to valid prescriptions from physicians when in fact they were not.

239. A claim seeking reimbursement for the dispensing of a drug is not eligible for payment by Federal Healthcare Programs if the dispensation is not supported by a valid prescription. Under Medicare, a Part D Sponsor "may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. §423.104(h). A "valid prescription" is defined as "a prescription that complies with applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100. Similarly, Medicaid coverage only extends to "prescribed drugs," and does not include drugs dispensed pursuant to invalid prescriptions. 42 U.S.C. § 1396d(a)(12).

240. As described above in paragraphs 26 to 65, when a pharmacy dispenses a prescription drug to a Federal Healthcare Program beneficiary, the pharmacy submits a claim to

the Government Payor, sometimes through a PBM, which processes the claim for payment. Typically, the pharmacy's claim submission includes basic information about the dispensation, including the beneficiary's name, the prescriber, the date the prescription was written, how the prescription was transmitted to the pharmacy (*i.e.*, by telephone or fax), the quantity dispensed, the number of refills authorized, the number of times the prescription has been filled, the amount claimed, and information on drug coverage under the Federal Healthcare Program. The Government Payor relies upon the accuracy of the claim information to make payment decisions.

241. With respect to Medicare Part D specifically, the Part D sponsor is then required to submit to CMS the PDE data based on the information the pharmacy provided, which includes the prescriber of the drug, how the prescription was transmitted to the pharmacy, the number of times the prescription was filled, the quantity dispensed, the amount paid to the pharmacy, and information on drug coverage under the Federal Healthcare Program. CMS relies on this information to assess the appropriateness of claim payments made by the Plan D Sponsor.

242. Federal Healthcare Programs require that pharmacies dispense prescription drugs pursuant to valid prescriptions, and the submission of complete, accurate, and truthful claims information by pharmacies like Omnicare is a condition of payment for such dispensations.

243. Omnicare routinely dispensed prescription drugs after the number of authorized refills (if any) were exhausted, after the prescription expired, or based on otherwise invalid records. When seeking payments for such dispensations, Omnicare falsely reported information indicating that Omnicare had obtained a valid prescription authorizing the dispensation.

244. The information Omnicare submitted in support of its claims for payment was derived from Omnicare's OmniDX and Oasis computer dispensing systems. And, for each drug

dispensed without valid authorization, Omnicare's computer dispensing systems set forth information regarding prescriptions that had expired or run out of refills and was therefore no longer accurate, or it set forth information that was otherwise false because Omnicare had failed to obtain a valid prescription in the first place. In addition, OmniDX generated false information, including the date on which the prescription was supposedly written and the supposed number of authorized refills, when prescriptions "rolled over."

245. Because the prescription-related information Omnicare provided in its claims for payment was derived from OmniDX and Oasis, each claim for drugs Omnicare dispensed without valid prescriptions contained false information about (1) the purported prescriber; (2) the date the supposed prescription was purportedly written; (3) the means by which the supposed prescription was received by the pharmacy; (4) the number of refills purportedly authorized; (5) the number of times the supposed prescription had been filled; and (6) the coverage for the dispensation under the Federal Healthcare Program. This false information—including the artificial computer-generated date or computer-generated number of allowable refills—made it look like the dispensations were supported by valid prescriptions, when in fact, the underlying prescriptions had expired or were otherwise invalid.

246. Government Payors made payment decisions based on this information submitted by Omnicare. With respect to Medicare, specifically, after the Plan D sponsor made its payment determinations based on Omnicare's false claims data, the Plan D sponsor submitted a subset of that false information to CMS, namely, the identity of the prescriber, the manner in which the prescription was transmitted to Omnicare, the number of times the prescription had been filled, and information on drug coverage under the Federal Healthcare Program.

247. Furthermore, as described above, the certifications and attestations signed and submitted by Omnicare certified compliance with applicable state and federal laws and CMS instructions. Omnicare's practice of violating federal and state laws by routinely dispensing prescription drugs to individuals in Residential Facilities without valid authorization rendered those certifications and attestations false.

248. Omnicare received federal funds to which it was not entitled as a result of presenting or causing to be presented false claims and making or causing to be made false statements and records concerning dispensations of prescription drugs without valid authorization.

V. Defendants' Fraudulent Conduct Was Material To Federal Healthcare Programs' Payment Decisions.

249. Whether a prescription drug is dispensed pursuant to a valid prescription is material to Federal Healthcare Programs' decision whether to pay for the drug. If the Federal Healthcare Programs had known that Omnicare systematically dispensed prescription drugs without valid prescriptions, the Federal Healthcare Programs would not have paid for Omnicare's illegal dispensations.

250. Indeed, the Federal Healthcare Programs (and the Plan D sponsors) conduct audits of pharmacies, in part, to determine whether pharmacies like Omnicare have obtained valid prescriptions to support their drug dispensations.

251. For instance, CMS conducts regular audits to determine whether dispensations of prescription drugs were billed appropriately to Medicare Part D plans and ultimately to CMS. As part of these audits, referred to as Part D PDE Validation audits, CMS requires Plan D sponsors to provide valid documentation showing proper authorization for an identified sample number of

prescription drug dispensations.

252. Omnicare's own audit department acknowledged that CMS audits are particularly stringent in enforcing requirements for what constitutes valid prescription documentation to support a drug dispensation. According to Omnicare's audit specialist, CMS did not accept "rollover" prescriptions. CMS required signed prescriptions that authorized a specific number of refills or explicitly provided that the prescription was valid for a specific period of time. And CMS rejected any prescription orders written more than twelve months before the date of the dispensation.

253. If Omnicare failed to produce valid authorization for dispensations, Plan D sponsors attempted to recoup the amount claimed for the dispensations. In addition, the Part D sponsor would reverse the PDE submission for that claim so it would not receive payment for that claim from CMS. CMS would not have paid for drugs if it knew the dispensations were not supported by current, valid prescriptions.

254. In its guidance for audits, CMS notes that pharmacies like Omnicare must maintain all records of prescriptions for 10 years. In fact, in connection with audits involving Medicare Part D claims, Omnicare is often reminded of its obligation to "maintain valid, signed physician's orders," which "must be retained by the pharmacy for the minimum timeframe required according to federal and state laws."

255. In addition, CMS's audit guidance provides examples of the types of documents that are considered valid prescriptions, including an image of a document setting forth the patient's name and date of birth, the date of the prescription, the name of the drug, information about the dose, directions for use, quantity, and number of refills, along with the prescriber's

name and signature. CMS's audit guidance also provides examples of unacceptable documentation, including documents that Omnicare improperly relied upon to dispense drugs such as the patient's prescription history, a computer-generated record reflecting the pharmacy's transaction for the dispensation, refill request lists, and medication administration records.

256. Furthermore, the accuracy, completeness, and truthfulness of all claims data is a condition of payment under the Federal Healthcare Programs. As such, Omnicare's repeated submission of false claims information making it appear that the claim was supported by a current, valid prescription was material to the Federal Healthcare Programs' payment decisions.

257. And as set forth above, Omnicare is required to certify compliance with federal and state laws regarding the dispensation of prescription drugs. As such, Omnicare's practice of violating federal and state laws by routinely dispensing prescription drugs to individuals in Residential Facilities without valid authorization is material to the Federal Healthcare Programs' payment decisions.

VI. False Claims Submitted By Omnicare

258. By dispensing prescription drugs to residents of Residential Facilities without valid prescriptions, Omnicare knowingly presented, or caused to be presented, hundreds of thousands of false claims to Federal Healthcare Program during the Relevant Period. These dispensations were not eligible for payment.

259. Attached as Exhibit 5 to the Complaint are examples of Omnicare dispensations of drugs to 41 Medicare beneficiaries without valid prescriptions, resulting in over 4,000 false claims. The Medicare beneficiaries resided in Rollover Residential Facilities. The exhibit includes the name, address, and internal identification number of the facility, as that information

appears in Omnicare's computer dispensing system; the name of the Omnicare pharmacy that dispensed drugs to the beneficiary; the name of each drug that was dispensed without a current, valid prescription or other authorization; and the dates of each invalid dispensation.²

260. Each claim submitted in connection with the dispensations listed in Exhibit 5 was false and not eligible for payment.

261. In addition, the information transmitted to the Government Payors in connection with these false claims was inaccurate and represented that Omnicare had current valid prescriptions for the dispensations when Omnicare did not. Specifically, Omnicare misrepresented the date the purported underlying prescription was written, the number of refills authorized under the purported prescription, and the number of times the purported prescription had been filled. Omnicare also misrepresented that a physician had written a valid prescription for the dispensation and that a valid prescription had been transmitted to Omnicare (via fax, telephone, etc.) when, in fact, there was no current, valid prescription. For example:

262. Omnicare of Annapolis Junction dispensed Amlodipine to Patient MA while he lived at a Residential Facility located in Maryland called My Own Place. Amlodipine is used to treat high blood pressure. Patient MA's physician wrote a prescription for Amlodipine in February 2015 and authorized two refills. Omnicare of Annapolis Junction dispensed Amlodipine to Patient MA beyond April 2015, and continued to dispense the drug on a monthly basis through at least December 2016, without obtaining a new prescription.

² The names and social security numbers of each beneficiary have been redacted from Exhibit 5, and the beneficiaries are referred to in this section by their initials. The Government will provide Defendants an unredacted version of the exhibit. Upon request, the Government will also provide an unredacted version of the exhibit to the Court.

263. Omnicare of Northern Massachusetts dispensed Risperidone to Patient PB while she lived at Hillside Rest Home, a Residential Facility in Amesbury, Massachusetts. Risperidone is an atypical antipsychotic used to treat schizophrenia. In October 2012, Hillside Rest Home sent the Omnicare pharmacy an “Interim Physician’s Order Sheet” listing Risperidone as one of 10 medications taken by Patient PB. The form contained the following language: “Unless otherwise stated all orders are valid for 30-60-90 days.” In a different section, the form stated: “These orders are in effect for one year unless otherwise designated or limited by law.” The form was not signed by a physician, nor did it contain any indication of the total quantity prescribed or authorized refills. Based on this document, Omnicare of Northern Massachusetts dispensed Risperidone to Patient PB for more than two years, until February 2015.

264. Omnicare of Northern California dispensed Carbamazepine to Patient JC through its cycle fill system while Patient JC lived at the Gramercy Court ALF in Sacramento, California. Carbamazepine is an anticonvulsant that requires periodic blood drug level monitoring to avoid toxicity. Patient JC’s physician wrote a prescription for Carbamazepine in September 2013 that authorized five refills. Patient JC was 64 years old at the time. Omnicare of Northern California continued to dispense Carbamazepine to Patient JC after the prescription expired on a monthly basis from October 2014 through February 2015 without obtaining a new prescription.

265. Omnicare of Chandler in Arizona dispensed Aripiprazole and Mirtazapine through its cycle fill system to Patient CC while she lived at Olive Grove Assisted Living in Phoenix, Arizona. At the time, Patient CC was taking at least five other drugs. Aripiprazole is an antipsychotic medication used to treat schizophrenia and bipolar disorder, and has an FDA black box warning regarding an increased risk of death when used by elderly patients with dementia.

Mirtazapine is an antidepressant used to treat major depressive disorder. Omnicare of Chandler received a signed physician's order for Aripiprazole and Mirtazapine in November 2011 authorizing 12 refills for each drug. However, from December 2012 through January 2014, the pharmacy continued to dispense Aripiprazole and Mirtazapine to Patient CC eight separate times each, without receiving a new prescription for either drug.

266. Omnicare of Wichita dispensed Carvedilol to Patient RB while he lived at the Presbyterian Manor Wichita Assisted Living Community in Wichita, Kansas. Carvedilol is a cardiovascular drug used to treat hypertension that requires monitoring for heart rhythm abnormalities and high blood sugar. At the time of Omnicare's dispensation in 2013, Patient RB was 77 years old and was taking more than ten other drugs. In October 2013, the assisted living facility sent Omnicare a fax noting that Patient RB was "a new resident in Assisted Living," along with a medication administration record ("MAR"), which listed the patient's drugs and how often he took each drug. The patient's MAR did not provide for authorized refills or total prescribed quantity, nor was it signed by a prescriber. Nevertheless, based on this document, Omnicare of Wichita dispensed Carvedilol for more than two years, until November 2015.

267. Omnicare of Cincinnati dispensed Atenolol to Patient MB while she lived at the Christian Village at Mount Healthy, an assisted living facility in Cincinnati, Ohio. Atenolol is used to treat high blood pressure and can cause dizziness and fainting. For more than three years—from January 2012 until April 2015—Omnicare of Cincinnati dispensed Atenolol based only on an unsigned Refill Medication Order sent by the ALF on January 29, 2010. At the time of the first dispensation in 2012, Patient MB was 89 years old, and was taking at least six other drugs.

268. Omnicare of Albuquerque dispensed Lisinopril to Patient MT while she lived at the Avamere at Rio Rancho, a Residential Facility in Albuquerque, New Mexico. Lisinopril is used to treat hypertension, and can cause dizziness and drowsiness, increasing the risk of falls in elderly patients. In February 2011, Patient MT's doctor wrote a prescription for Lisinopril and authorized refills as needed. Patient MT was 89 years old at the time and was taking several other medications. Based on the February 2011 prescription, Omnicare of Albuquerque dispensed Lisinopril to Patient MT well after the prescription expired in February 2012—from March 2012 until July 2014.

269. Omnicare of Billings in Montana dispensed Metoprolol and Furosemide through its cycle fill system to Patient LP while he lived at Sierra Hills, an assisted living facility in Cheyenne, Wyoming. Furosemide is a diuretic that requires periodic blood work to monitor kidney function and avoid dehydration. Metoprolol is a cardiovascular drug used to treat hypertension that can cause abnormal low blood pressure and dizziness, increasing the risk of falls in elderly Patients. Omnicare of Billings received a prescription for Furosemide dated December 2011 authorizing the dispensing of a three-month supply of the medication (90 tablets) and two refills (for a total prescribed quantity of 270 tablets). At the time, Patient LP was 88 years old and was taking many other drugs. Omnicare of Billings continued to dispense Furosemide to Patient LP pursuant to the December 2011 prescription, from October 2012 through October 2014, for a total of two years, without receiving a new prescription. In addition, Omnicare of Billings received a prescription for Metoprolol dated January 2012 authorizing two refills. However, after exhausting these refills, Omnicare of Billings continued to dispense Metoprolol to Patient LP thirteen separate times without receiving a new prescription.

270. Omnicare of Oklahoma City and Omnicare of Tulsa dispensed Memantine, a drug used to treat dementia associated with Alzheimer’s disease, to Patient MB2 while she lived at the Brookdale Cedar Ridge Assisted Living Facility. Memantine can cause renal failure stroke and hemorrhage. In September 2012, the ALF sent Omnicare a “Refill Rx” form, requesting a refill for Memantine 10mg. Patient MB2 was 78 years old at the time, and was taking at least five other medications. Based on this document only—and without any current prescription—Omnicare of Oklahoma City and Omnicare of Tulsa dispensed Memantine to Patient MB2 for well over a year, from September 2012 until February 2014.

271. Omnicare of San Diego dispensed Divalproex through its cycle fill system to Patient GN while he lived at Alpine Terrace, a Residential Facility in Alpine, California. Divalproex is an anticonvulsant medication that requires periodic blood drug level monitoring to avoid toxicity. Omnicare of San Diego received a “Telephone Order” for Divalproex in January 2012 authorizing 5 refills. Patient GN was 58 years old at the time. After exhausting these refills, Omnicare of San Diego continued to dispense Divalproex to Patient GN ten separate times, through January 2014, without receiving a new prescription.

COUNT I

Violations of the FCA: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

272. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

273. The United States seeks relief against Defendants under 31 U.S.C. § 3729(a)(1)(A).

274. Through the acts set forth above, Defendants knowingly, or acting with deliberate

ignorance or reckless disregard of the truth, presented, either directly or indirectly, false or fraudulent claims for payment to Government Payors in connection with the dispensation of prescription drugs. Specifically, Defendants knowingly, or acting with deliberate ignorance or reckless disregard of the truth, presented false or fraudulent claims for reimbursement for the dispensation of prescription drugs that were not authorized by valid prescriptions and consequently were not eligible for reimbursement.

275. The Government Payors made payments to the Defendants because of the false or fraudulent claims.

276. If the Government Payors had known that the claims presented for payment were for the dispensation of prescription drugs that were not authorized by valid prescriptions, they would not have paid the claims.

277. By reason of these false or fraudulent claims, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

COUNT II

Violations of the FCA: Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

278. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

279. The United States seeks relief against Defendants under 31 U.S.C. § 3729(a)(1)(B).

280. Through the acts set forth above, Defendants knowingly, or acting with deliberate ignorance or reckless disregard of the truth, made, used or caused to be made or used false

records and statements material to the payment of false or fraudulent claims by Government Payors. Specifically, Defendants knowingly, or acting with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used false or fraudulent records and statements — in the form of, *inter alia*, false claims data, false certifications, and false attestations — that were material to the payment of false or fraudulent claims for reimbursement for the dispensation of prescription drugs that were not authorized by valid prescriptions.

281. If the Government Payors had known that the records and statements were false, they would not have paid the claims.

282. By reason of these false records and statements, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

COUNT III

Violations of the FCA: Failure to Repay Government Funds (31 U.S.C. § 3729(a)(1)(G))

283. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

284. The United States seeks relief against Defendants under 31 U.S.C. § 3729(a)(1)(G).

285. Through the acts set forth above, Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government by knowingly failing to repay the Government Payors the payments Defendants had received for dispensing prescription drugs that were not authorized by valid prescriptions, once Defendants became aware that Omnicare pharmacies had been routinely dispensing drugs to

residents of ALFs and other Residential Facilities after prescriptions had expired or any authorized refills had been exhausted.

286. By reason of Defendants' failure to repay these funds, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

COUNT IV

Payment by Mistake of Fact

287. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

288. The United States seeks relief against Defendants to recover monies paid under mistake of fact.

289. The Government Payors paid Defendants for claims in connection with the dispensation of prescription drugs based on the mistaken and erroneous belief that the dispensations were authorized by valid prescriptions. This erroneous belief, as well as the false representations and records made by Defendants concerning the claims, were material to the determination to pay for the claims.

290. If the Government Payors had known that the claims were for the dispensation of drugs not authorized by valid prescriptions, they would not have paid the claims

COUNT V

Unjust Enrichment

291. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

292. Through the acts set forth above, Defendants have received payments to which they were not entitled and therefore have been unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, Defendants should not retain those payments, the amount of which is to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests judgment to be entered in its favor as follows:

- a. On Counts I, II, and III (FCA violations), a judgment against Defendants for treble damages and civil penalties to the maximum amount allowed by law.
- b. On Count IV and V (Payment by Mistake of Fact and Unjust Enrichment), a judgment against Defendants for damages to the extent allowed by law.
- c. Costs and such other relief as the Court may deem appropriate.

Dated: New York, New York
December 17, 2019

Respectfully submitted,

GEOFFREY BERMAN
United States Attorney for the
Southern District of New York

By: Mónica P. Folch
JEFFREY K. POWELL
MÓNICA P. FOLCH
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel.: (212) 637-2800
jeffrey.powell@usdoj.gov
monica.folch@usdoj.gov

Counsel for the United States